

The Validity and Sensitivity of Rheumatoid Arthritis Pain Scale on a Different Ethnic Group From Indian Rheumatoid Arthritis Patients

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ABSTRACT

Objectives: This study aims to assess pain in rheumatoid arthritis (RA) patients by using Rheumatoid Arthritis Pain Scale (RAPS) and to find its correlation with Disease Activity Score 28 (DAS28) and Clinical Disease Activity Index (CDAI).

Patients and methods: The study included 100 RA patients (23 males, 77 females; mean age 43.22 years; range, 19 to 72 years) who were subjected to RAPS questionnaire for pain assessment and DAS28 and CDAI for disease activity assessment. Spearman's correlation coefficient was measured to assess the correlation of RAPS with DAS28 and CDAI. Cronbach's alpha (α) was also measured for each scale to assess reliability.

Results: The study group had a female to male ratio of 3.34:1. Mean values for RAPS, DAS28 and CDAI were 62.91, 5.59, and 25.24, respectively. RAPS was correlated with DAS28 and CDAI with correlation coefficients of 0.811 and 0.770, respectively. Cronbach's α for RAPS, DAS28 and CDAI were 0.892, 0.814, and 0.833, respectively.

Conclusion: Rheumatoid Arthritis Pain Scale had a strong positive correlation with disease activity measures of DAS28 and CDAI. RAPS also showed good correlation with core data set measures hence merits its place in clinical practice.

Keywords: Clinical Disease Activity Index, Cronbach's alpha, disease activity score 28, Rheumatoid Arthritis Pain Scale, Spearman's correlation coefficient.

Rheumatoid arthritis (RA) is a chronic, multisystemic, immune-mediated inflammatory disease characterized by articular and extra-articular manifestations along with systemic manifestations in the form of generalized malaise and fatigue.¹ It exhibits a chronic fluctuating course, which may result in recurrence of symptoms, progressive joint damage, deformity and disability.¹ Typical symptoms of RA are multiple joint pain, early morning stiffness and joint swelling, but out of these, pain is the most common reason for seeking medical care as observed in various

studies.²⁻⁴ Joint pain in RA is diffuse aching and burning that is usually moderately severe, and usually intermittent with exacerbations and remissions.⁵ Pain is the outcome of its four components, i.e. physiological, affective, sensory-discriminative, and cognitive.⁵ RA patients mainly present in clinics or outpatient departments with the complaint of pain, which may be mild to severe in intensity. Rheumatoid Arthritis Pain Scale (RAPS) is a self-reported pain assessment scale, which is easy to use and which assesses almost all aspects of RA pain.⁵ Only limited

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data are available on RAPS use in RA patients and to our knowledge, no Indian study has been performed to date. Therefore, in this study, we aimed to assess pain in RA patients by using RAPS and to find its correlation with Disease Activity Score 28 (DAS28) and Clinical Disease Activity Index (CDAI).

PATIENTS AND METHODS

The study was conducted at Department of Rheumatology, Pt. B. D. S. Post Graduate Institute of Medical Sciences between July 2014 to April 2015 and included 100 RA patients (23 males, 77 females; mean age 43.22 years; range, 19 to 72 years) diagnosed as per American College of Rheumatology (ACR) 1987 criteria⁶ and who were able to read and write. Patients who were severely anemic, had hypothyroidism or evidence of liver, renal, pulmonary or cardiac disease were excluded. The study protocol was approved by the institutional Ethics Committee. A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

All patients were assessed for both patient- and physician-derived parameters. Patient-derived parameters were pain visual analog scale (VAS) and patient’s global assessment (PGA) of disease activity whereas physician-derived parameters were tender joint count (TJC), swollen joint count (SJC) and evaluator’s global assessment (EGA) of disease activity. Erythrocyte sedimentation rate (ESR) was also measured for each patient. Disease activity measures of DAS28 and CDAI were calculated by using these baseline parameters.

All patients were asked to complete the RAPS questionnaire simultaneously and to score each question from 0 (never) to 6 (always). Total RAPS score was calculated by simple summation of individual item’s score ranging from 0 to 6 totaling between 0 and 144 with higher scores indicating more pain. There is no cut-off limit to define mild, moderate and severe pain in RAPS score.⁵

Statistical analysis

Data were statistically analyzed using IBM SPSS version 20.0 software (IBM Corp., Armonk,

NY, USA). Spearman’s correlation coefficient was calculated to interpret relationships between two variables. The strength of correlation as per norms was classified into nil (zero), fair (0.1-0.25), moderate (0.25-0.50), strong (0.5-0.8), and very strong to perfect (0.8-1). P values of less than 0.05 was considered as statistically significant. All patients were distributed into four groups as per quantification of disease severity assessed by

Table 1. Mean values with standard deviation of various parameters

Parameters/variable	Mean±SD
TJC (0-28)	8.8±5.7
SJC (0-28)	6.3±3.9
PGA (0-100 mm)	57.±18.8
EGA (0-100 mm)	49.0±17.5
Pain VAS (0-100 mm)	5.7±1.9
ESR (0-200 mm/hour)	43.8±20.0
DAS28 (0-9.4)	5.6±1.2
CDAI (0-76)	25.2±11.2
RAPS (0-144)	62.9±22.0

SD: Standard deviation; TJC: Tender joint count; SJC: Swollen joint count; PGA: Patient’s global assessment; EGA: Evaluator’s global assessment; VAS: Visual analog scale; ESR: Erythrocyte sedimentation rate; DAS28: Disease activity score 28; CDAI: Clinical Disease Activity Index; RAPS: Rheumatoid Arthritis Pain Scale.

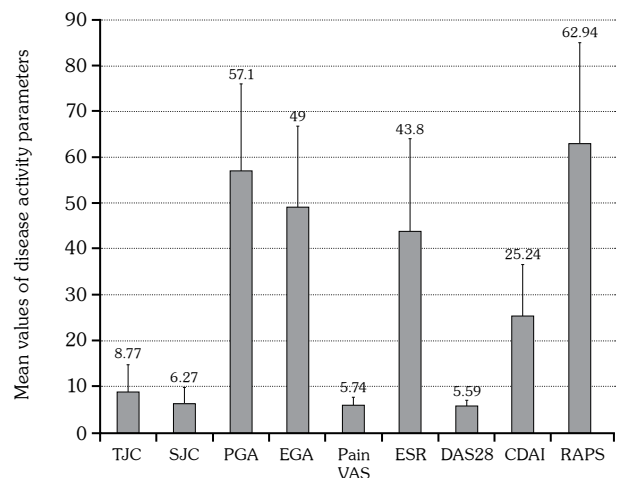


Figure 1. Column chart showing values within one standard deviation of mean for various disease activity parameters.

TJC: Tender joint count; SJC: Swollen joint count; PGA: Patient’s global assessment; EGA: Evaluator’s global assessment; VAS: Visual analog scale; ESR: Erythrocyte sedimentation rate; DAS28: Disease activity score 28; CDAI: Clinical Disease Activity Index; RAPS: Rheumatoid Arthritis Pain Scale.

Table 2. Correlation of RAPS with DAS28

Severity	Number of patients		DAS28		RAPS		CC	
	n		Mean±SD		Mean±SD		p	p
Remission	1		2.5±0.0		21±0.0			
Low	3		3.0±0.1		23.3±6.0		0.894	<0.001
Moderate	31		4.4±0.6		45.5±13.8		0.660	<0.001
High	65		6.3±0.7		73.7±17.1		0.585	<0.001
Overall	100		5.6±1.2		62.9±2.0		0.811	<0.001

RAPS: Rheumatoid Arthritis Pain Scale; DAS28: Disease activity score 28; CC: Correlation coefficient; SD: Standard deviation; Disease severity as per disease activity score 28: remission=0-2.6; mild=2.61-3.2; moderate=3.21-5.1; severe=5.11-9.4; p<0.05: Significant.

Table 3. Correlation of RAPS with CDAI

Severity	Number of patients		CDAI		RAPS		CC	
	n		Mean±SD		Mean±SD		p	p
Low	13		7.9±2.2		34.4±16.8		-0.09	>0.05
Moderate	28		18.1±3.0		51.8±15.4		0.46	<0.05
High	59		32.5±8.0		74.5±16.7		0.62	<0.05
Overall	100		25.2±11.2		62.9±22.0		0.770	<0.001
Overall	100		5.6±1.2		62.9±2.0		0.811	<0.001

RAPS: Rheumatoid Arthritis Pain Scale; CDAI: Clinical Disease Activity Index; CC: Correlation coefficient; SD: Standard deviation; Disease severity as per Clinical Disease Activity Index: remission=0-2.8; mild=2.81-10.0; moderate=10.1-22.0; severe=22.1-76; p<0.05: Significant.

DAS28 and CDAI. Mean values of DAS28, CDAI and RAPS for each category and correlation between the two variables were also assessed. All patients were reassessed at third month follow-up using DAS28 and CDAI while they were also subjected to complete RAPS. Then, the correlation between RAPS change and the change in disease activity was assessed. Cronbach's alpha (α) was calculated for RAPS, DAS28, and CDAI to assess the reliability.

RESULTS

In the study group, there were 77 females and 23 males, with a female to male ratio of 3.34:1. Mean age of study population was 43.22±10.4 years and mean duration of disease was 55.9±50.6 months. Rheumatoid factor (RF) positivity was found in 82 patients.

The mean values of various parameters, disease activity indices, and RAPS are shown

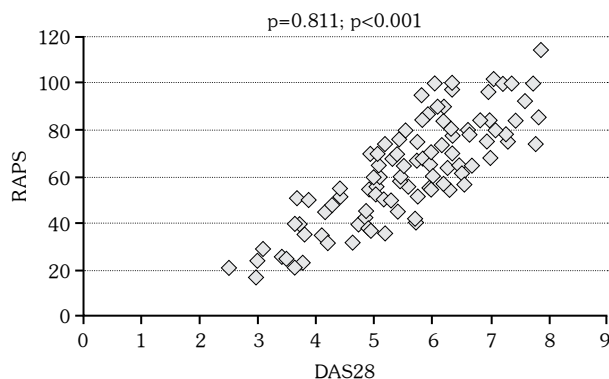


Figure 2. Correlation of RAPS with DAS28.

RAPS: Rheumatoid Arthritis Pain Scale; DAS28: Disease activity score 28.

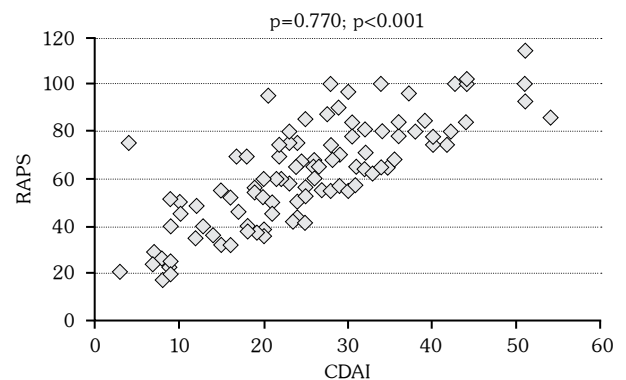


Figure 3. Correlation of RAPS with CDAI.

RAPS: Rheumatoid Arthritis Pain Scale; CDAI: Clinical Disease Activity Index.

Table 4. Correlation of RAPS with changes in disease activity

Mean RAPS change		Disease activity change		Disease activity change		
RAPS		DAS28		CDAI		CC
Mean±SD		Mean±SD		Mean±SD	p	p
-28.74±11.54		-1.3±0.5		-11.1±5.8	0.837	<0.001

RAPS: Rheumatoid Arthritis Pain Scale; DAS28: Disease activity score 28; CC: Correlation coefficient; CDAI: Clinical Disease Activity Index; SD: Standard deviation; p<0.05: Significant.

in Table 1 and Figure 1. RAPS was found to be correlated significantly with DAS28 (Spearman’s correlation coefficient [ρ]=0.811, $p<0.001$) and CDAI ($\rho=0.770$, $p<0.001$) (Tables 2, 3 and Figures 2, 3).

Rheumatoid Arthritis Pain Scale was found to be correlated strongly with DAS28 and CDAI in patients who had moderate to severe disease activity (Tables 2, 3). At low disease state, RAPS had fair correlation with DAS28 whereas it was very poorly correlated with CDAI (Tables 2, 3). Correlation of RAPS with DAS28 and CDAI could not be established at remission state due to the inadequate number of subjects (Tables 2, 3).

To evaluate the efficacy for RAPS in term of correlation of its value change with the disease activity change, we re-assessed the RAPS, DAS28 and CDAI at third month follow-up and found a strong positive correlation between RAPS change and changes in DAS28 ($\rho=0.896$, $p<0.001$) and CDAI ($\rho=0.837$, $p<0.001$) (Table 4; Figures 4, 5).

When RAPS was compared statistically with other core data set measures including TJC, SJC, PGA, EGA, pain VAS, and ESR, it was found to be correlated statistically significantly with coefficients (ρ) of 0.753, 0.594, 0.674, 0.614, 0.641, and 0.676, respectively (all $p<0.01$) (Table 5).

DISCUSSION

Pain in RA is the most difficult variable to be quantified as it varies from person to person. It is the major factor for seeking medical attention and determining change in treatment in patients of RA. Pain is a core efficacy set measure for clinical research hence its evaluation becomes necessary. A study by Pincus and Sokka highlighted the importance of pain over joint counts or laboratory parameters in the assessment of disease.⁷ Multiple factors play role in pain experience as a whole like ethnicity, memory, age, religion, and socio-economic environment.

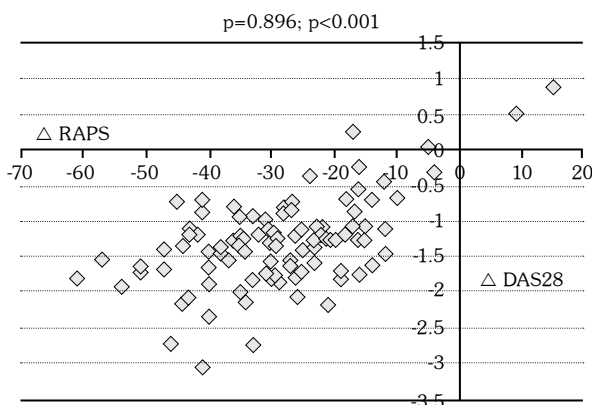


Figure 4. Correlation of RAPS change (Δ RAPS on X-axis) with DAS28 change (Δ DAS28 on Y-axis).
RAPS: Rheumatoid Arthritis Pain Scale; DAS28: Disease activity score 28.

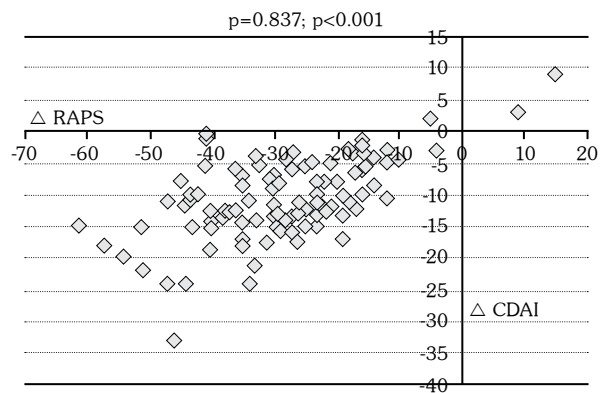


Figure 5. Correlation of RAPS change (Δ RAPS on X-axis) with CDAI change (Δ CDAI on Y-axis).
RAPS: Rheumatoid Arthritis Pain Scale; CDAI: Clinical Disease Activity Index.

Table 5. Correlation of RAPS with various core data set parameters

Parameters	Spearman's rho	p
Tender joint count	0.753	<0.001
Swollen joint count	0.594	<0.001
Patient's global assessment	0.674	<0.001
Evaluator's global assessment	0.614	<0.001
Pain visual analog scale	0.641	<0.001
Erythrocyte sedimentation rate	0.676	<0.001

RAPS: Rheumatoid Arthritis Pain Scale; rho: Correlation coefficient; p<0.05: Significant.

Pain is a complex process in RA and is not always correlated with disease activity particularly when the disease activity or inflammation is settled. In the initial phases of RA, pain results

from inflammation, as evidenced by tenderness and swelling of the joints as well as laboratory findings such as increased C-reactive protein and ESR, anemia, or thrombocytosis. Presence of RF is also consistent with inflammation. As RA progresses, the damaging effect of erosion of cartilage and bone also causes pain. When the inflammatory process is settled, the joint involved may be damaged so that it is mechanically unstable and more likely to undergo degenerative changes that further contribute to pain.⁸

Pain management is one of the components of treatment strategies in RA as effective pain control may provide enhanced compliance of patients to therapy and participation in physical activity. Therefore, pain assessment as well as other objective features need to be considered

Table 6. Rheumatoid Arthritis Pain Scale questionnaire⁵

No	Pain items	Possible range
1	I would describe my pain as gnawing.	0-6
2	I would describe my pain as aching.	0-6
3	I would use the word exhausting to describe my pain	0-6
4	I would describe my pain as annoying.	0-6
5	I am in constant pain	0-6
6	I would describe my pain as rhythmic	0-6
7	I have swelling of at least one joint.	0-6
8	I have morning stiffness of one hour or more.	0-6
9	I have pain on motion of at least one joint.	0-6
10	I cannot perform all the everyday tasks I normally would because of pain.	0-6
11	Pain interferes with my sleep.	0-6
12	I cannot decrease my pain by using methods other than taking extra medication.	0-6
13	I would describe my pain as burning.	0-6
14	I find that I guard my joints to reduce pain.	0-6
15	I brace myself because of the pain.	0-6
16	My pain is throbbing in nature.	0-6
17	I would describe my pain as sharp.	0-6
18	I would say my pain is severe.	0-6
19	I feel stiffness in my joints after rest.	0-6
20	My joints feel hot.	0-6
21	I feel anxious because of pain.	0-6
22	I would describe my pain as tingling.	0-6
23	I feel my pain is uncontrollable.	0-6
24	I feel helpless to control my pain.	0-6

Physiological component: Items 7, 8, 9, 19, and 20.

Affective component: Items 3, 4, 14, and 15.

Sensory-discriminative component: Items 1, 2, 5, 6, 13, 16, 17, 18, and 22.

Cognitive component: Items 10, 11, 12, 21, 23, and 24.

Rheumatoid Arthritis Pain Scale Score=sum of individual scores of 24 items.

while determining the treatment. To ensure this, a single reliable scoring system is required that assesses pain. However, complete assessment of pain is a difficult task since a very limited number of tools have been designed to date to capture all domains of pain. The existing pain assessing instruments are general assessment measures and are neither specific to RA nor do they reflect the fluctuating and recurrent nature of chronic pain related to this disease. The traditional methods of measurement include simple descriptive scales, modified VASs, numeric rating scales (NRSs), multidimensional scales, and verbal rating scales, such as the McGill Pain Questionnaire (MPQ), which can be generalized to a variety of pain syndromes.

Although pain VAS is the most commonly used tool to assess pain intensity, it does not appear to suffice in current clinical practice where treatment interventions depend upon how well the pain is controlled. Similar to the pain VAS, the pain NRS evaluates only one component of the pain experience such as pain intensity and therefore does not capture the complex and idiosyncratic nature of the RA pain or improvements due to symptom fluctuations.

On the other hand, RAPS (Table 6) is a tool designed specifically for RA encompassing the cognitive appraisals, sensory phenomenon, behavioral disturbances, and physiological factors in a single instrument.⁵ RAPS was developed in 2001 by Anderson⁵ in view of perceiving pain in all dimensions and conferring specificity for RA; however, its use to date has been restricted to certain ethnic groups. This scale is simple to use unlike MPQ, which is full of complex vocabulary and may not be appropriate for patients with low literacy.⁹ RAPS is more comprehensive than pain VAS and may play a complimentary role in capturing multiple domains of pain.¹⁰

In a study by Kianifard et al.¹¹ on Indian patients, RAPS demonstrated modest correlation with DAS28 while no correlation was studied with CDAI. However, in the present study, we found that RAPS showed strong positive correlation with both disease activity measures of DAS28 and CDAI.

Rheumatoid Arthritis Pain Scale also correlated well with the ACR core data measures of ESR, pain VAS, SJC, TJC, PGA, and EGA. According

to a study of Anderson et al.,² RAPS was shown to correlate with TJC ($\rho=0.5237$, $p<0.01$) and pain VAS ($\rho=0.6756$, $p<0.01$) whereas another study by Kianifard et al.¹¹ demonstrated no correlation between RAPS and pain VAS while showing fair correlation between RAPS and SJC. In our study, we found good correlation between RAPS and baseline disease activity parameters of ESR, pain VAS, SJC, TJC, PGA, and EGA (Table 5).

The reason for the different results in our study might be due to the fact that majority of the patients in our study either presented at advanced stage of the disease (Tables 1, 2) or due to their more subjective perception of pain.

We also calculated the internal consistency (Cronbach's α) to measure the reliability of RAPS. The Cronbach's α for RAPS was 0.892, whereas it was 0.814 and 0.833 for DAS28 and CDAI, respectively, showing significantly higher reliability for RAPS compared to DAS28 and CDAI.

Correlation of RAPS with the changes including improvement or worsening of disease activity was also assessed in our study and RAPS was detected to have strong positive correlation with the changes in disease activity as assessed by DAS28 and CDAI (Table 4). Hence, our study demonstrated that as disease activity scores increased, RAPS score increased and vice versa and treatment brought changes in both disease activity and pain scores.

Thus, in our study, despite excluding joint counts and other physician-derived components, the RAPS has been shown to correlate with joint counts, EGA, ESR measures on an individual basis as well as with other composite measures (e.g. DAS28, CDAI) that contain such items. We also found that RAPS has high reliability, acceptability, feasibility, and sensitivity to detect any improvement or deterioration in RA disease activity. Hence, this instrument can be used in routine clinical care to follow-up patients of RA and to distinguish clinically effective therapies from the ineffective ones. Comprehensive pain assessment using this instrument can lead to more effective pain management and better physical rehabilitation.

The limitations of our study include the single-center design on a relatively small study population. Moreover, although the study group

was representative of the center's entire RA patient population, the majority of patients had moderate to severe disease activity. Furthermore, fibromyalgia that coexists in 15-20% of RA patients could have exerted an influence on pain perception.¹² In addition, pain is highly subjective and its perception varies from individual to individual. Patient issues may be more related to pain whereas physician's main concern is reduction of disease activity.

In conclusion, RAPS had strong positive correlation with disease activity assessment tools as well as with other disease activity parameters. RAPS seems to be a highly reliable and clinically valuable measure to assess pain as well as disease activity comprehensively in RA patients. We suggest further larger studies with longer follow-ups to assess the long-term efficacy of RAPS in the follow-up of RA.

Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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