

Chinese registry of rheumatoid arthritis: IV. Correlation and consistency of rheumatoid arthritis disease activity indices in China

Xing Song¹, Yan-Hong Wang², Meng-Tao Li³, Xin-Wang Duan⁴, Hong-Bin Li⁵, Xiao-Feng Zeng³, the Co-authors of CREDIT

¹Peking Union Medical College and Chinese Academy of Medical Sciences, Beijing 100730, China;

²Department of Epidemiology and Bio-statistics, Institute of Basic Medical Sciences, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing 100005, China;

³Department of Rheumatology, Peking Union Medical College Hospital (PUMCH), Peking Union Medical College & Chinese Academy of Medical Sciences, National Clinical Research Center for Dermatologic and Immunologic Diseases (NCRC-DID), Ministry of Science & Technology, Key Laboratory of Rheumatology and Clinical Immunology, Ministry of Education, State Key Laboratory of Complex Severe and Rare Diseases, Ministry of Science & Technology, Beijing 100730, China;

⁴Department of Rheumatology, The Second Affiliated Hospital of Nanchang University, Nanchang, Jiangxi 330006, China;

⁵Department of Rheumatology, The Affiliated Hospital of Inner Mongolia Medical College, Hohhot, Inner Mongolia 010050, China.

Abstract

Background: Disease activity indices (DAIs) including disease activity score 28 (DAS28), simplified disease activity index (SDAI), and clinical disease activity index (CDAI) have been widely used in clinical practice and research studies of rheumatoid arthritis (RA). The objective of our study was to evaluate the correlation and concordance among different DAIs in Chinese patients with RA.

Methods: A cross-sectional study, including patients enrolled in the Chinese registry of rheumatoid arthritis from November 2016 to August 2018, was conducted. The correlations were evaluated using Spearman correlation coefficient and concordance with Bland-Altman plots, quadratic weighted kappa, and discordance rates in the crosstab. For other indices, the optimal cutoff points corresponding to SDAI remission were explored through receiver operating characteristic curve analysis.

Results: A total of 30,501 patients were included, of whom 80.46% were women. Most individuals were with moderate disease activity or high disease activity. High correlations among DAS28-erythrocyte sedimentation rate (ESR) and DAS28-C-reactive protein (CRP), SDAI and CDAI were observed. Similarly, the weighted kappa value among the indices was high. In Bland-Altman plots, a positive difference between DAS28-ESR and DAS28-CRP was observed, with an absolute difference of >1.2 in 3079 (10.09%) patients. In crosstab, approximately 30% of the patients were classified into different groups. Concordance values between SDAI remission and the optimal cutoff points of DAS28-ESR, DAS28-CRP, and CDAI were 3.06, 2.37, and 3.20, respectively.

Conclusions: Although DAIs had high correlations and weighted kappa values, the discordance between DAIs was significant in Chinese patients with RA. The four DAIs are not interchangeable.

Keywords: Disease activity indices; Rheumatoid arthritis; Chinese registry of rheumatoid arthritis

Introduction

Rheumatoid arthritis (RA) is a common inflammatory joint disease, affecting 1% of the world's population.^[1] It is characterized by persistent inflammatory synovitis. Failure to control inflammation over time causes cartilage damage, bone erosion, and joint ankylosis, leading to joint deformities and functional loss.^[2] To effectively control the disease to achieve remission, the disease activity must be accurately evaluated, and the disease activity index (DAI) can help to judge the improvement and guide

treatment. Currently, the evaluation of RA is not obtained from a single index. The criteria used to evaluate RA are composite indices. Disease activity score 28 (DAS28), simplified disease activity index (SDAI), and clinical disease activity index (CDAI) are commonly used in clinical practice, but there is no generally accepted "gold standard."^[3]

Different indices can categorize the same patient into different disease activity groups, leading to differences in treatment. Therefore, previous studies comparing RA DAIs have been numerous.^[4-7] Some studies have

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Correspondence to: Xiao-Feng Zeng, Department of Rheumatology, Peking Union Medical College Hospital (PUMCH), Beijing 100730, China
E-Mail: zengxfpumc@163.com

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suggested that the cutoff values of some indices should be adjusted, while other studies have suggested that the formulas for calculating indices should be revised, adding some factors, including sex, age, disease duration, and so on.^[8,9] Some studies have suggested that different regions and races might have differences in DAIs; in particular, the cutoff value of DAS28-C-reactive protein (CRP) in Asia might be reduced, so DAIs should be compared in different regions.^[5,10,11]

Many countries have performed their own studies of RA DAIs.^[9-12] The results of the reports have been inconsistent. RA patients exceed 5 million in China, but there remains a lack of research in this field.^[13] Since 2016, Peking Union Medical College Hospital (PUMCH) has led the establishment of the Chinese registry of rheumatoid arthritis (CREDIT) database (the first nationwide, multi-center, online, disease-based RA registry in China).^[14] Using the related information in the CREDIT database, we compared the following RA DAIs: DAS28-erythrocyte sedimentation rate (ESR), DAS28-CRP, SDAI, and CDAI. The aim was to analyze the correlation and consistency of the DAIs and to explore the indices' thresholds as "suitable for Chinese."

Methods

Ethical approval

Ethics approval for the registry was obtained from the Medical Ethics Committee of PUMCH (No. JS-2038), which was accepted by all of the participating centers as the central institutional review board. Informed consent was obtained from all of the patients at enrollment.

Study design

Multicenter baseline data were selected from the CREDIT database from November 2016 to August 2018 for a cross-sectional study. The database contains information about RA patients in more than 500 hospitals in 26 provinces, autonomous regions, and municipalities in China. All of the hospitals are Class A tertiary hospitals, with independent departments of rheumatology and immunology, and the doctors participating in the evaluation are rheumatic specialists. These doctors have been trained and have practiced for many years, so the evaluation of RA disease activity is relatively objective and standard. Patients older than 16 years were selected to meet the 2010 American College of Rheumatology (ACR) classification criteria for RA diagnosis,^[15] and the relevant data and examination results were complete. Patients with other autoimmune diseases or acute infections were excluded from this study.

The study variables mostly included sex, age, disease duration, pain visual analog scale (VAS), physician's global VAS, patient's global VAS, 28-tender joint count, 28-swollen joint count, ESR, high-sensitivity CRP, rheumatoid factor (RF), DAS28-ESR, DAS28-CRP, SDAI, and CDAI. The above information was collected, calculated, and saved in accordance with the requirements of the CREDIT database. Laboratory examinations were per-

formed in designated laboratories according to uniform standards.

After careful data review, 152 patients younger than 16 years and 2159 cases with other autoimmune diseases or acute infections or incomplete core data were excluded from the data analysis. Quantitative parametric data were expressed using mean and standard deviations, while non-parametric data were expressed in medians and inter-quartile ranges (IQRs). Qualitative data were expressed in numbers and percentages. Most of the data were not normally distributed and were analyzed using Spearman correlation. The concordance between clinometric indices was assessed by quadratic weighted kappa value, for which patients were classified into the ordinal categories of disease activity according to the cutoff points proposed by ACR/European League Against Rheumatism (EULAR). Non-concordant percentages were calculated by the number of misclassified people divided by the total number. Moreover, the Bland-Altman plot was constructed to examine agreement between the DAS28 measures.^[16] According to previous reports, a difference of >0.6 between the DAS28-ESR and DAS28-CRP was considered greater than measurement error, and a difference >1.2 was clinically significant.^[9,11] Therefore, instead of using the mean and standard deviation, cutoffs of $(\pm) 0.6$ and $(\pm) 1.2$ were used to denote the limits of agreement in the plots. In addition, we used the ACR/EULAR 2010 RA definition of remission^[17]: SDAI ≤ 3.3 was set as the standard, and we used the receiver operating characteristic (ROC) curve to analyze DAS28 and CDAI; the optimal cutoff point was determined using the maximum Youden index. SPSS (version 23.0, SPSS Inc., Chicago, IL, USA) was used for data analysis, and a two-sided P value < 0.05 was considered statistically significant.

Results

General characteristics

The characteristics of the RA patients included in the study are shown in Table 1. A total of 24,541 (80.46%) patients were female. The mean age of the patients was 52.6 ± 13.1 years, and the median disease duration was 4 (1, 10) years. Of the patients, 84.70% were seropositive for RF. According to the DAIs, approximately 80% of the patients had moderately and highly active disease. The mean DAS28-ESR and DAS28-CRP scores of the patients were 5.1 ± 1.7 and 4.5 ± 1.6 , respectively, and the median (IQR) of the SDAI and CDAI were 24.6 (14.9, 39.7) and 22.5 (13.5, 36.8), respectively.

DAIs as continuous variables

Table 2 shows that there was a high correlation among all four index scores; the correlation coefficients were all >0.9 ($P < 0.001$). The correlation between SDAI and CDAI had the highest correlation coefficient: $\rho = 0.989$.

The mean DAS28-ESR and DAS28-CRP scores of the patients were 5.1 ± 1.7 and 4.5 ± 1.6 , respectively [Ta-

Table 1: Demographic, clinical, and laboratory characteristics of 30,501 RA patients.

Characteristics	Results
Female, <i>n</i> (%)	24,541 (80.46)
Age (years), mean ± SD	52.6 ± 13.1
Disease duration (years), median (IQR)	4 (1, 10)
RF, <i>n</i> (%)	25,834 (84.70)
TJC, median (IQR)	3 (1, 8)
SJC, median (IQR)	3 (1, 7)
Pain VAS (0–10 scale), mean ± SD	4.49 ± 2.58
PtGA (0–10 scale), mean ± SD	4.62 ± 2.47
PhGA (0–10 scale), mean ± SD	4.11 ± 2.39
ESR (mm/1 h), median (IQR)	32 (17, 56)
CRP (mg/L), median (IQR)	9.4 (3.0, 25.0)
DAS28-ESR, mean ± SD	5.1 ± 1.7
DAS28-CRP, mean ± SD	4.5 ± 1.6
SDAI, median (IQR)	24.6 (14.9, 39.7)
CDAI, median (IQR)	22.5 (13.5, 36.8)

CDAI: Clinical disease activity index; CRP: C-reactive protein; DAS28: Disease activity score 28; ESR: Erythrocyte sedimentation rate; IQR: Interquartile range; PhGA: Physician global assessment; PtGA: Patient global assessment; RA: Rheumatoid arthritis; RF: Rheumatoid factor; SDAI: Simplified disease activity index; SJC: Swollen joint count; TJC: Tender joint count; VAS: Visual analog scale.

Table 2: Correlations among DAS28, SDAI, and CDAI.

Items	DAS28-ESR	DAS28-CRP	SDAI	CDAI
DAS28-ESR	–	0.951*	0.920*	0.911*
DAS28-CRP	0.951*	–	0.955*	0.935*
SDAI	0.920*	0.955*	–	0.989*
CDAI	0.911*	0.935*	0.989*	–

* $P < 0.001$. CDAI: Clinical disease activity index; CRP: C-reactive protein; DAS28: Disease activity score 28; ESR: Erythrocyte sedimentation rate; SDAI: Simplified disease activity index.

ble 1]. The mean DAS28-ESR was significantly higher than the mean DAS28-CRP ($P < 0.001$). The Bland-Altman plots showed similar findings. Positive differences between DAS28-ESR and DAS28-CRP were observed in 83% of cases, and the average difference was 0.54 (95% confidence interval: 0.51–0.58). The plot [Figure 1] also showed that an absolute difference of ≤ 0.6 was observed in 14,993 patients (49.16%); 40.75% of the differences ranged from 0.6 to 1.2, and 10.09% were > 1.2 .

DAIs as categorical variables

Every DAI classified the disease into four same categories: remission, low disease activity (LDA), moderate disease activity (MDA), and high disease activity (HDA). Four DAI pairwise comparisons are presented in cross tables [Table 3; Supplementary Tables 1–5, <http://links.lww.com/CM9/A547>]. The weighted kappa score between DAS28-CRP and CDAI was the lowest (weighted kappa = 0.637), and the score between SDAI and CDAI was the highest (weighted kappa = 0.895). Almost all of the weighted kappa scores were > 0.6 ($P < 0.001$), representing that the

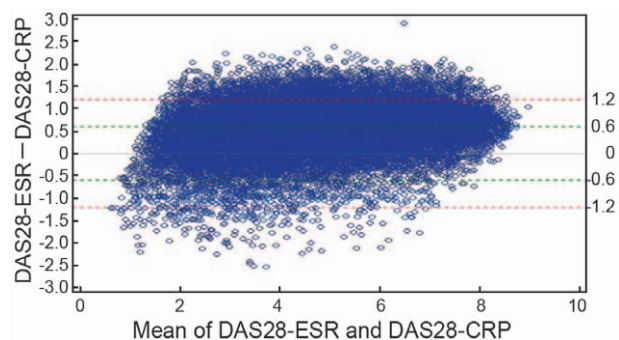


Figure 1: Bland-Altman plot analysis of DAS28. The x-axis represents the mean of DAS28-ESR and DAS28-CRP; the y-axis represents the difference between DAS28-ESR and DAS28-CRP. CRP: C-reactive protein; DAS28: Disease activity score 28; ESR: Erythrocyte sedimentation rate.

four indices had good consistency in classifying disease activity categories.

Stated differently, approximately 30% of the patients with different DAIs belonged to different groups [Table 3; Supplementary Table 1, <http://links.lww.com/CM9/A547>]. The proportion of discordance between SDAI and CDAI was lowest (8.70%), and the proportion between DAS28-CRP and CDAI was highest (32.79%). While comparing DAS28-ESR and DAS28-CRP, 28.96% of patients were in different groups, 25.94% of patients were assigned to a higher disease activity group, and 3.02% were assigned to a lower group using DAS28-ESR. Similarly, comparing SDAI and CDAI, 6.07% of patients were assigned to a higher disease activity group, and 2.63% were assigned to a lower group using CDAI. Between DAS28-ESR and SDAI, 25.7% were in different groups, 13.4% of patients were assigned to a higher disease activity group, and 12.3% were assigned to a lower group using SDAI. We suggested that the DAIs' conservative rank was DAS28-CRP $<$ DAS28-ESR $<$ SDAI $<$ CDAI.

Indices' performance over the standard reference index (SDAI ≤ 3.3)

Figure 2 shows the ROC curves for the DAS28-ESR, DAS28-CRP, and CDAI remission threshold values that corresponded to SDAI ≤ 3.3 . The optimal remission cutoff values were 3.06, 2.37, and 3.20 for the DAS28-ESR, DAS28-CRP, and CDAI, respectively.

Discussion

This study is the first comprehensive comparative study of RA patients' DAIs in mainland China using the CREDIT database. The study included 30,501 RA patients who met the enrollment criteria and were included in the database from 26 provinces in China since 2016.^[14,18] Unlike previous studies, the majority of the study population were in remission and LDA, and we know that most of our population was in MDA or HDA. Unlike conventional clinical trials, this study was entirely a non-interventional study of real-world RA patients, so the results can be well applied to clinical practice.

Table 3: Consistency analysis between DAS28-ESR and DAS28-CRP.

DAS28-ESR	DAS28-CRP				Weighted kappa
	Remission	LDA	MDA	HDA	
Remission	2047	290	99	0	0.6822*
LDA	1043	701	302	0	
MDA	577	2153	8224	233	
HAD	0	3	4136	10,693	

* $P < 0.001$. The patients' numbers of different disease activity groups based on two DAIs appear in the table. The numbers on the diagonal from the top left to the bottom right are the numbers of patients in the same disease activity groups. Non-concordant rate = (total number - number grouped consistent)/total number. This group was 28.97%; other groups underwent the same calculation method. CRP: C-reactive protein; DAS28: Disease activity score 28; ESR: Erythrocyte sedimentation rate; HDA: High disease activity; LDA: Low disease activity; MDA: Moderate disease activity.

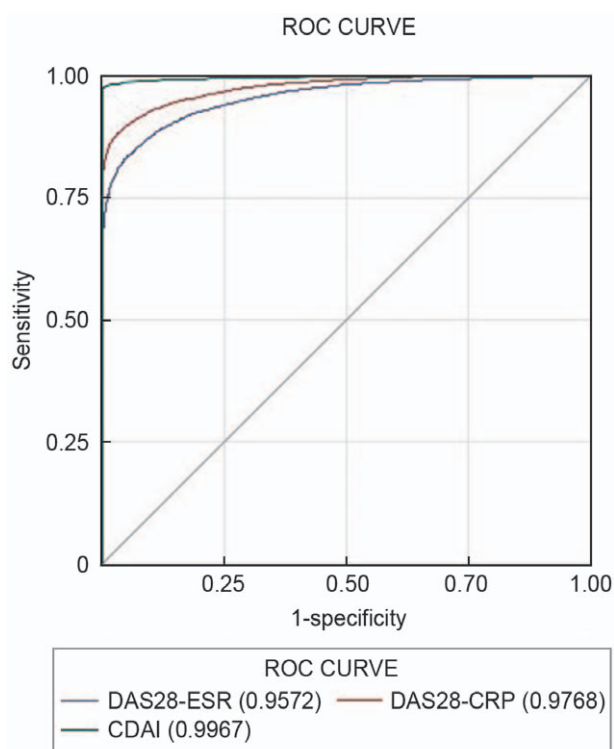


Figure 2: ROC curves for DAS28-ESR (AUC 0.9572), DAS28-CRP (AUC 0.9768), and CDAI (AUC 0.9967) according to the ACR/EULAR gold standard index-based definition of remission (SDAI ≤ 3.3). Concordance values between SDAI remission and the optimal cutoff points of DAS28-ESR, DAS28-CRP, and CDAI were 3.06, 2.37, and 3.20, respectively. AUC: Area under curve; CDAI: Clinical disease activity index; CRP: C-reactive protein; DAS28: Disease activity score 28; ESR: Erythrocyte sedimentation rate; ROC: Receiver operating characteristic; SDAI: Simplified disease activity index.

Similar to previous studies,^[7,8,12] there were high correlations among the four DAIs in Chinese RA patients, with Spearman rho > 0.9 . Compared with previous studies, the correlation between DAIs was 0.7 to 0.9, which was higher in China. Everyone seems to agree that a high degree of correlation does not imply a high degree of consistency. Many studies have used kappa coefficients to analyze the consistency between DAIs, but the kappa results have been quite different, and opposite conclusions have been obtained. In some studies,^[5,9,19] the kappa coefficients

were 0.3 to 0.5, and the consistency between DAIs was fair, while in other studies,^[7,8] the values were approximately 0.8, so the conclusions regarding consistency between DAIs have been various. For these reasons, previous studies have generally explained the differences in disease status among the subjects involved. However, we believe that the main reason for the differences was that different studies have used different statistical methods to calculate kappa values. The result calculated by the simple kappa method was obviously lower than that of the weighted kappa method. Then, the same consistency standard was used to evaluate the results, so different conclusions were drawn. Because the variables were multiple ordered (remission, LDA, MDA, and HDA), we believe that the weighted kappa method was more appropriate. On this basis, we obtained the results that the weighted kappa between DAIs were 0.6 to 0.8, and the values were highly consistent.

Interestingly, although there were obvious differences in consistency analysis, all of the studies agreed that DAIs were not interchangeable. Although those results were highly correlated and highly consistent among DAIs, the conclusions were also the same. Some studies used Bland-Altman plots to analyze why DAIs were not interchangeable. In this study, the absolute difference between DAS28-ESR and DAS28-CRP was > 1.2 in 10.09% of the patients, with $> 5\%$ suggesting that DAS28-ESR and DAS28-CRP were not interchangeable. This outcome was consistent with previous studies. The plot also showed that 83% of patients had DAS28-ESR greater than DAS28-CRP, with an average difference of 0.54. A conclusion similar to previous studies was obtained: compared with DAS28-ESR, DAS28-CRP might underestimate the disease state and overestimate the treatment efficacy, and the threshold of DAS28-CRP might be down-regulated. In addition, we would also like to mention that the Bland-Altman method is inappropriate for comparing the consistency between SDAI and CDAI for methodological reasons.^[10]

If we discussed whether DAIs were interchangeable, we believe that DAIs are mainly categorical variables, rather than continuous variables. Therefore, the cross tables and the non-consistent ratios might better reflect the classification differences between indices. Previous studies have reported that the proportion of inconsistencies among the four DAIs can reach up to 50%.^[7,10] In our study, approximately 30% of the patients were grouped differently by different DAIs. We further compared the inconsistencies of each group using the cross tables and found that SDAI and CDAI were more conservative than DAS28 in evaluating the disease state. This outcome is similar to what Gaujoux-Viala *et al*^[3] reported: “the main limitation of the DAS28 is a broader definition of remission.” Therefore, we also suggest that the four indices are not interchangeable.

Since the indices are not interchangeable, many studies have considered some ways to improve the grouping consistency between indices; the common way has been to revise the cutoff values for DAIs. The re-definition of the optimal remission cutoff values is an exploratory attempt. There is no consensus on how to revise the current cutoff

values. We set SDAI ≤ 3.3 as the standard and used ROC curves to determine the new remission thresholds for DAS28-ESR, DAS28-CRP, and CDAI. SDAI ≤ 3.3 is considered the remission standard for the following two reasons. (1) Compared with the DAS28, the SDAI formula is simpler, and previous studies have shown that the SDAI is more conservative than the DAS28. Therefore, similar articles have mostly chosen the SDAI as the standard. (2) We chose this standard to render our results comparable with other foreign studies. Our results were different from most previous studies. Analyzing the reasons, the study population and the patients' disease states were different. Moreover, the analytical methods used were different. In Fleischmann research, three methods were used to calculate the average value, and the ROC curve analysis obtained higher cutoff values using the maximum Youden index. Our purpose is to prove that the same patient is categorized into different disease activity groups according to different DAI cutoff values. Considering one index as the standard, the calculated cutoff values of other indices are quite different from the current criteria. Therefore, different indices are not interchangeable, and we might also attempt to evaluate the conservatism of each DAI.

In addition, some studies have suggested revising the formula for DAS28. Others have suggested that factors that could affect DAIs, such as sex and age, be added to the formula. However, all of the authors noted that these were only suggestions and required further validation in large samples and different populations. Here, we must point out that assessing the entire population is almost impossible, so developing a universal formula is difficult. Moreover, a potential problem of amending or adding more variables to the existing formula is that it could cause the DAIs to become more complicated, thereby reducing their use in clinical practice. Considering the clinical practical application, the SDAI and CDAI have great advantages because of their simple formulas, and they might also be easier to understand by patients and might therefore enhance adherence to treatment regimens.

Our study had several limitations. First, this study was a cross-sectional study, and it was not possible to compare the effects of different DAIs on disease improvement and analyze the evolution of disagreements over time. Second, China is a multi-ethnic country, and our study did not group by race, so it might have ignored the impact of ethnic minorities on DAIs.^[20] Finally, we did not consider other possible confounding factors as grouping variables, such as treatment, course of the disease, etc.

To conclude, based on a large number of detailed and accurate data from the CREDIT database, we analyzed and compared the four DAIs of RA patients in China for the first time. There is a high degree of correlation and large weighted kappa values among RA DAIs in China. However, approximately 30% of the patients were grouped differently by different DAIs, which could lead to a discrepancy in treatment, so we believe that the DAIs are interchangeable. The SDAI and CDAI are more conservative than the DAS28 in evaluating the disease state. Considering the purpose of targeted treatment, the SDAI and CDAI might be more reliable and convenient

than DAS28. In the future, more follow-up studies of DAIs in assessing treatment improvement should be performed.

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Conflicts of interest

None.

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