



Application of disease activity index in rheumatoid arthritis management in Korea

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Effective management of rheumatoid arthritis (RA) necessitates the accurate measurement of disease activity using a treat-to-target strategy established as a cornerstone approach. Disease activity assessment tools such as the Disease Activity Score in 28 joints (DAS28), Simplified Disease Activity Index, Clinical Disease Activity Index, and Routine Assessment of Patient Index Data 3 have been internationally validated and recognised. In Korea, the government initiated a quality assessment program mandating routine measurement of DAS28 to ensure high-quality RA management. However, whether the DAS28 is the most suitable disease activity measurement tool in the Korean clinical environment is a topic worth considering. In this review, we comprehensively examined disease activity measurement tools and their performance in the Korean context. We also propose a new strategy for measuring RA disease activity, tailored to the different situations encountered by physicians in routine clinical practice. This review may contribute to the improvement of the quality of care for patients with RA in Korea.

Keywords: Rheumatoid arthritis, Severity of illness index, Outcome assessment, Korea

INTRODUCTION

Rheumatoid arthritis (RA) is the most common inflammatory polyarthritis characterised by symmetrical involvement of the peripheral joints, which causes joint deformity and progressive physical disability [1]. Its global prevalence is approximately 0.5%, although it varies considerably among populations [2]. In Korea, the estimated prevalence of RA ranges from 0.27% to 1.85% [3], and the incidence rate is approximately 28.5~42.0 per 100,000 person-years [4,5]. The degree of functional impairment in RA affects both the health-related quality of life (HRQoL) and economic burden of the illness [6]. RA contributes the most to the total direct medical cost of autoimmune inflammatory rheumatic diseases in Korea and has been rapidly increasing over time [7].

The primary goals of RA management are to achieve long-term HRQoL through symptom control, prevention of structural damage, and normalisation of function [8]. To achieve this goal, the treat-to-target (T2T) strategy was introduced in 2010 [9]. The basic concept of the T2T strategy is to intensify treatment until the target is reached, which is defined as remission or low disease activity (LDA) [9]. Adherence to the T2T strategy is superior to conventional therapeutic approaches for RA in improving functional disabilities and structural damages [10]. The official guidelines for RA management from the European Alliance of Associations for Rheumatology (EULAR) and the American College of Rheumatology (ACR) have endorsed the T2T strategy since the concept was first presented in 2010 [11,12] and remain valid in their latest versions [13,14].

To adhere to the T2T strategy, the International Task Force

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recommends that quantitative measures of disease activity be obtained and documented regularly in routine clinical practice [8]. The routine use of disease activity measures may be required by payers or governments to demonstrate good quality of care [15]. Because of the efforts of the Korean College of Rheumatology and rheumatologists in Korea, the Disease Activity Score in 28 joints (DAS28) became reimbursable from October 2023 onwards, laying the foundation for implementing the T2T strategy in clinical practice. In line with the DAS28 reimbursement, the Health Insurance Review and Assistance (HIRA), a Korean government agency, began quality assessments for RA management in April 2024 to provide effective medical services to Korean patients with RA. The indicators included early prescription of disease-modifying antirheumatic drugs (DMARDs), regular monitoring of laboratory tests, uninterrupted prescription of DMARDs, regular measurement of disease activity, and the proportion of patients achieving remission or LDA. The DAS28 method was selected for measuring disease activity and determining remission or LDA.

This study aimed to review the performance of RA disease activity measurements in the Korean population and evaluate the strengths and weaknesses of each tool in the Korean healthcare environment. Additionally, we aimed to anticipate the advantages and disadvantages of RA disease evaluation based on the DAS28 and discuss how the utilisation of disease assessment tools should be expanded in various contexts.

MAIN SUBJECTS

Performance of disease activity measures in patients with rheumatoid arthritis

Since the first composite disease activity measurement tool for RA was developed in the 1950s [16], RA disease activity monitoring has been improved. Amid this proliferation of measurement tools, the ACR committee has provided guidelines indicating which RA disease activity measures are best suited for regular use [17,18]. The initial 2012 recommendations included six RA disease activity measures as follows: Clinical Disease Activity Index (CDAI), DAS28, Patient Activity Scale (PAS), Patient Activity Scale-II (PAS-II), Routine Assessment of Patient Index Data 3 (RAPID3), and Simplified Disease Activity Index (SDAI) [17]. The recommendations updated in 2019 [18] were largely unchanged from those previously recommended, although the PAS was not recommended for preferred use in the

updated recommendations.

The following section summarises the reliability of disease activity measurement tools for patients with RA, with a particular focus on the Korean population. PAS and PAS-II, which are not commonly used in the Korean population, were excluded.

1) DAS28 with erythrocyte sedimentation rate or C-reactive protein

The DAS28 based on erythrocyte sedimentation rate (DAS28-ESR) is one of the most historic and widely used measures that have been extensively validated in western populations for its use in clinical trials and practice [19-24]. In the Korean population, a lower DAS28-ESR score was associated with better HRQoL and less functional disability in patients with RA [25]. RA management using the T2T strategy targeting remission or LDA based on the DAS28-ESR significantly improved functional outcomes compared to usual care in Korean patients [26].

Although the DAS28-ESR inherently possesses characteristics as a reference standard, the performance of DAS28 based on C-reactive protein level (DAS28-CRP) in the Korean population mostly has been compared with that of the DAS28-ESR. The DAS28-CRP levels had a strong linear correlation with DAS28-ESR (correlation coefficient: 0.87~0.93), indicating its validity as a disease activity measure [27-29]. However, the DAS28-CRP levels were lower than the DAS28-ESR within the same study populations [28,29], and the comparison of disease activity categories based on DAS28-ESR and DAS28-CRP levels showed suboptimal agreements (Cohen's κ : 0.40~0.45). Thus, although the DAS28-CRP levels can reliably measure RA disease activity, they may underestimate disease activity compared with DAS28-ESR.

2) Simplified disease activity index and clinical disease activity index

Since the SDAI and CDAI were originally developed and validated in western populations [30], these indices demonstrated excellent correlations with the DAS28 in other populations [31,32]. The SDAI and CDAI also had a strong linear correlation with the DAS28-ESR in Korean patients with RA, with correlation coefficients of 0.85 and 0.84, respectively [27]. However, disease activity categories based on SDAI or CDAI showed discrepancies from those based on DAS28-ESR [27]. In particular, remission as defined by the SDAI or CDAI was more stringent than DAS28 remission. For example, the remission rates in Ko-

rean patients treated with biologic or targeted synthetic (b/ts) DMARDs ranged from 10% to 13% based on the SDAI or CDAI and from 36% to 56% based on the DAS28 [33]. Thus, the SDAI and CDAI are comparable with the DAS28-ESR as indicators of disease activity in Korean patients with RA, although they are more stringent in classifying patients as having achieved remission.

3) Routine assessment of patient index data 3

Several studies in different ethnic populations have demonstrated that RAPID3 provides similar information regarding disease activity as other quantitative disease activity instruments, such as DAS28, CDAI, or SDAI [34-36]. In Korean patients with RA, RAPID3 scores significantly correlated with DAS28 (correlation coefficient: 0.62), SDAI (correlation coefficient: 0.74), and CDAI (correlation coefficient: 0.75) [37]. However, the agreement of disease activity in remission to low-activity status demonstrated a discrepancy. For example, approximately 90% of patients who showed moderate or high disease activity according to the DAS28, CDAI, and SDAI also exhibited moderate or higher disease activity when assessed using the RAPID3 criteria. Meanwhile, only 50% of patients who were classified as having LDA or remission using other methods showed LDA when assessed using the RAPID3. Thus, the RAPID3 reflects disease activity, although it has better agreement with other disease activity tools in patients with higher disease activity than in those with lower disease activity.

Preferred disease activity measures for routine clinical use in Korea

DAS28-ESR, DAS28-CRP, CDAI, SDAI, and RAPID-3 all comparably reflected disease activity in Korean patients with RA, but with slight differences between each index, as described above. To date, rheumatologists have utilised various disease activity assessment tools, as permitted in clinical practice and research. However, owing to recently implemented reimbursement policies and quality indicators, the standardisation of a single measure, DAS28, is likely to have both benefits and drawbacks. Therefore, while not disputing the fact that the DAS28 is a qualified tool for disease activity assessment, how other useful disease activity measurements can be utilised needs to be considered.

1) Critical appraisal of routine measurements of DAS28

The DAS28 method is the most established composite measure for assessing RA disease activity. The DAS28 is familiar to both clinicians and administrators because the Korean National Health Insurance reimbursement criteria for b/tsDMARDs are based on disease activity in the DAS28 [38]. However, the major drawbacks of these methods include discrepancies between DAS28-ESR and DAS28-CRP levels and misclassification of disease activity in patients with certain phenotypes. There are also ongoing international efforts to address the limitations of DAS28 and improve its accuracy in assessing disease activity.

Clinicians may assume that DAS28 assessments based on ESR or CRP levels are interchangeable. The current policy of the HIRA for quality assessment adopts DAS28 as a standard disease activity measure without specifying whether ESR or CRP levels should be used. However, as mentioned earlier, DAS28-CRP levels tend to underestimate disease activity compared with DAS28-ESR in Korean patients with RA. These observations are not limited to Korean patients as these have also been consistently observed in other regions and ethnicities [39-41]. Conversely, DAS28-ESR may overestimate disease activity compared with DAS28-CRP levels, especially in female patients or those with longer disease duration [42]. Therefore, selecting DAS28 as a standard measurement in routine clinical practice without specifying DAS28-ESR or DAS28-CRP may result in a loss of continuity in the comparative assessments of disease activity. In addition, disease activity categories [27,43] and treatment responses [28] are inconsistently classified when DAS28-ESR and DAS28-CRP are used interchangeably.

Moreover, DAS28 may misclassify disease activity in patients with certain RA phenotypes. For example, patients using specific bDMARDs such as tocilizumab showed a discrepancy between disease activity measured by DAS28 and other disease activity indices. Korean patients with RA receiving tocilizumab were 5 to 7 times more frequently to achieve remission based on the DAS28, compared with assessment based on the SDAI or CDAI [33]. A significant proportion of patients treated with tocilizumab had at least two swollen joints when in DAS28 remission [33]. In another example, misjudgement for disease activity was also possible in patients with RA with ankle and foot joint involvement when using the DAS28. Korean patients with RA in DAS28 remission frequently have residual disease activity in the ankle and foot joints [44]. Overall, over 10% of patients in remission, as assessed by DAS28, had swollen joints in the foot

and/or ankle. Considering that a significant proportion of Korean patients with RA have foot and/or ankle involvement [45], their clinical significance should not be ignored.

Finally, DAS28 has faced criticism for not always aligning with the objectively measured degree of inflammation [46]. Among the four components of DAS28, the swollen joint count and the acute inflammation reactants better predicted imaging-confirmed synovitis than the other components—tender joint count and patient global assessment [47,48]. Therefore, some researchers have proposed modified DAS formulas that reweight these components, which have shown stronger associations with radiographic damage [47,48]. While the accuracy of these modifications has yet to be investigated in the Korean population, their potential benefit over the current DAS28 method warrant further study.

2) Disease activity measurements to be additionally used and their contexts in the era of DAS28

(1) Identification of patients with rheumatoid arthritis in remission

Although LDA and remission have similar statuses based on the T2T concept, remission is particularly important for identifying patients with better outcomes [49], who may be suitable for tapering DMARDs [14]. The clinical significance of RA remission is the absence of signs and symptoms of significant inflammatory disease activity [9]. Physicians cannot rely on DAS28 criteria to determine remission because patients in DAS28 remission commonly experience residual joint inflammation [33,44,45]. In one study, up to 50% of patients in DAS28 remission showed active joint inflammation on ultrasonography [50]. Thus, DAS28 is no longer recommended for defining remission in the international guidelines [51].

In 2011, the ACR and EULAR established a new definition of remission using the Boolean approach, ensuring uniform reporting of outcomes [51]. The Boolean definition to attain remission was defined as each of four core variables (tender joint count, swollen joint count, patient global assessment [PtGA] of disease activity on a 0~10 cm, and CRP level in mg/dL) having a value of ≤ 1 . Analysis of pre-existing clinical trial data on patients with RA suggested that the Boolean criteria later predicted good radiographic and functional outcomes, although DAS28-based measures of remission did not [51]. Since then, the requirement of achieving a PtGA score of ≤ 1 has been criticised to be exces-

sively strict [52,53], and the updated ACR/EULAR remission definition (Boolean criteria 2.0) [54] has increased the threshold for PtGA to 2 cm. Boolean criteria 2.0 maintained its predictive value for radiographic or functional outcomes and improved the agreement between the Boolean criteria and other index-based remission criteria [54].

Therefore, the use of Boolean remission criteria instead of DAS28 in our clinical practice may be worth considering, aligning with updates in international guidelines [14,51]. Further research is needed to confirm whether Boolean remission enhances long-term outcomes in Korean patients.

(2) Adjustment of treatments based on disease activity

If a patient exhibits disease activity that exceeds low levels, disease activity measurements serve to guide treatment adjustments [9]. The T2T approach targeting DAS28 LDA or remission results in superior radiographic and functional outcomes compared with the standard routine care for RA [10]. Interestingly, a recent meta-analysis indirectly has showed that a T2T strategy aimed at SDAI-LDA was superior to one aimed at DAS28-LDA in achieving remission according to the DAS28, SDAI, or Boolean criteria [55]. Nonetheless, no significant differences in HRQoL or radiographic progression were observed between the two strategies [55]. Therefore, a systematic study is required to determine the optimal criteria for treatment modification in Korean patients with RA. Currently, various disease activity assessment tools can be used; nevertheless, consistently using a single method is necessary to track changes in disease activity. In particular, the interchangeable use of DAS28-ESR and DAS28-CRP levels for assessment should be avoided.

(3) Disease activity measurements in the telehealth settings

The first two scenarios assumed face-to-face patient encounters in a clinic, which has been the norm to date. However, the coronavirus disease 2019 pandemic has highlighted the need to care for patients with RA in telehealth settings [56]. Most studies on telemedicine for RA have evaluated disease activity using DAS28 as an outcome after adopting consultation-based telemedicine as an adjuvant for in-person visits [57]. However, studies that remotely assess composite disease activity to make therapeutic decisions via telemedicine have been limited to date [58].

Recently, disease activity indices such as DAS28 and CDAI have been adopted to better accommodate telehealth contexts

by substituting provider joint counts with patient-assessed joint counts and omitting acute-phase reactants [56]. The development and validation of these modified versions are warranted in the forthcoming telemedicine era. Measurements composed of patient-reported items such as RAPID3 are readily available and require minimal adjustments for use in telemedicine settings [56]. Although changes in RAPID-3 over time are not directly proportional to changes in other disease activity indices [59], it is as sensitive as DAS28 and CDAI in distinguishing active from control treatments in clinical trials [60]. Therefore, the feasibility and long-term impact of RAPID3 use in telehealth settings in Korea should be explored. Additionally, studies using advanced cameras and digital devices to accurately assess swelling and tenderness in 28 joints of patients and comparing these results with those of physician assessments need to be conducted.

CONCLUSION

Quantitative measures of disease activity are fundamental to the management of RA. Several disease activity measures, including DAS28-ESR, DAS28-CRP, SDAI, CDAI, and RAPID3 have been validated and compared in Korean patients with RA. Although DAS28-ESR and DAS28-CRP levels are widely used, discrepancies between them require careful consideration. SDAI, CDAI, and RAPID3 also performed excellently in reflecting disease activity and are comparable to DAS28. All indices can be used to optimise treatment based on disease activity; however, consistent use of a single measure is advised to avoid misclassification.

In this review, we summarised realistic expectations and concerns regarding the standardisation of DAS28. In particular, we provided suggestions on how to define remission and the application of disease activity measurements in telehealth settings. With the recent decision to reimburse DAS28 measurement, we anticipate significant improvements in clinical practice and patient outcomes for RA in Korea. This development is expected to enhance the precision of treatment adjustments and overall disease management. We believe that systematic research on these aspects is necessary in the future.

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CONFLICT OF INTEREST

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AUTHOR CONTRIBUTIONS

Y.K.S. and S.R.C. conceived of and designed the study. Y.K.S., S.K.C., and S.R.C. were responsible for data acquisition, analysis, and interpretation. S.R.C. drafted the manuscript. Y.K.S., S.K.C., and S.R.C. critically reviewed and revised the manuscript. All the authors approved the final version of the manuscript.

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