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## Study on sensitivity and specificity of diagnostic criteria for early rheumatoid arthritis

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**Abstract** Sensitivity and specificity were compared among the American College of Rheumatology (ACR) 1987 classification criteria, the Yamasaki diagnostic criteria, and the Japan Rheumatism Association (JRA) diagnostic criteria for early rheumatoid arthritis (RA). The study included 90 patients who consulted our department for the first time within 1 year after onset and were suspected of having RA (final diagnosis: RA 45 cases, non-RA 45 cases). We investigated whether physical and laboratory findings at the first examination met these three sets of criteria to determine the sensitivity and specificity of each set of diagnostic criteria. Moreover, the sensitivity and specificity of each item in the diagnostic criteria set were similarly determined. The sensitivity of the ACR 1987 classification criteria, the Yamasaki diagnostic criteria, and the JRA diagnostic criteria for early RA were 71.1%, 88.9%, and 95.6%, respectively, and their specificities were 100%, 93.3%, and 77.8%, respectively. In a study on each diagnostic item, observation for 1 week was considered to be sufficient for morning stiffness, swelling in three joint areas, and symmetrical swelling, while observation for a more prolonged period seemed to be necessary for swelling of the finger and hand joints. The Yamasaki diagnostic criteria are appropriate for the diagnosis of early RA, while the JRA diagnostic criteria are suitable for screening.

**Key words** Diagnostic criteria · Early rheumatoid arthritis · Rheumatoid arthritis

### Introduction

Recently, to prevent the progression of joint destruction in rheumatoid arthritis (RA), the necessity of initiating treatment during the early stage before joint destruction has been advocated. However, to treat RA, it is essential to obtain a definitive diagnosis. The diagnosis of RA is currently based on the classification criteria proposed by the American College of Rheumatology in 1987 (ACR criteria),<sup>1</sup> but this set of criteria is strict, and is therefore sometimes inappropriate for diagnosing early RA in which all symptoms have not yet appeared. In Japan, two sets of diagnostic criteria for early RA have been proposed by Yamasaki<sup>2</sup> and the Japan Rheumatism Association (JRA).<sup>3,4</sup>

The Yamasaki diagnostic criteria for early RA (Yamasaki criteria) are based on the ACR criteria. According to the results of a study of 26 patients with RA occurring within 1 year after onset, a diagnosis could be made within 2 months after onset, if the symptoms were monitored for 1 week. Involvement of the distal interphalangeal (DIP) joints, metatarsophalangeal (MTP) joints, and ankle joints were shown to have the greatest importance. The DIP joints were included in the list of three joint areas, and the ankle and MTP joints were included in the items related to hand arthritis. Because few patients demonstrated morning stiffness persisting more than 1 h, the duration was set to 15 min after referring to the ACR remission criteria.<sup>5</sup> There were no patients showing rheumatoid nodules during the early stage, and therefore this item was deleted (see Table 2).

With respect to the JRA diagnostic criteria for early RA (JRA criteria), two groups of patients were enrolled by JRA councillors and were studied comparatively: 123 RA patients and 61 patients with systemic rheumatic diseases other than RA occurring within 2 years after onset. Six clinical

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symptoms showed significant differences between the two groups (joint pain, joint swelling, morning stiffness, grip strength, involvement of the toe joint, and rheumatoid nodules), and four laboratory parameters (erythrocyte sedimentation rate, C-reactive protein (CRP), rheumatoid factors, and IgA), were examined in greater detail to prepare the new diagnostic criteria. These criteria were intended for simple screening during the early stage (see Table 3).

We undertook this study to evaluate the usefulness of these two sets of diagnostic criteria for early RA in comparison with that of the ACR criteria.

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## Patients and methods

### Patients

In this study, a diagnosis of early RA was reached when the patient had had symptoms for less than 1 year. The subjects were 90 patients who came to our department for the first time within 1 year after the onset of joint pain or stiffness of hands or feet between 1994 and 1996, and were suspected of having RA. Patients who had received treatment with an antirheumatic drug prior to the first examination at our department were excluded. Patients who fulfilled the ACR criteria during follow-up were diagnosed with RA. Patients who did not meet the ACR criteria but showed persistent swelling of a single joint, those who did not demonstrate joint swelling but showed multiple joint pain, and those who showed persistent morning stiffness for least 1 hour were listed as "suspected of having RA and progress was being followed." The final diagnosis was made by two or more certified rheumatologists. Patients were followed up for a minimum of 6 months.

The mean follow-up period was 2.0 years (7 months to 3.1 years). The final diagnoses, which were determined according to the ACR criteria, were RA in 45 patients (14 males, 31 females; mean age at first examination 55.3 years) and diseases other than RA in 45 patients (non-RA, 10 males, 35 females; mean age at the first examination 54.1 years). The latter included 18 patients with osteoarthritis (OA), 7 who were suspected of having RA and whose progress was being followed, 6 with tenosynovitis, 4 with carpal tunnel syndrome, 2 with lunatomalacia, 2 with gout, 1 with polymyalgia rheumatica, 1 with hepatitis, 1 with pseudogout, 1 with sternocostoclavicular hyperostosis, 1 with erythema nodosum, and 1 with cervical myelopathy. There was no difference in the male-to-female ratio or mean age between the two groups.

### Methods

For these 90 subjects, at 6 weeks after the first examination, we determined the sensitivities and specificities of the ACR criteria, the Yamasaki criteria, and the JRA criteria for early RA. In addition to the overall sensitivity and specificity of these criteria, those of each diagnostic item at the first examination were evaluated.

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## Results

### Overall sensitivity and specificity of the criteria

The sensitivity and specificity were 71.1% and 100%, respectively, for the ACR criteria. Those for the Yamasaki criteria were 88.9% and 93.3%, respectively, and those for the JRA criteria were 95.6% and 77.8%, respectively.

Seven of 45 non-RA patients met the Yamasaki criteria. Four of these had OA of the fingers, 2 were suspected of having RA and were being followed up, and 1 had polymyalgia rheumatica. Ten of the 45 non-RA patients satisfied the JRA criteria, including 5 with OA of the fingers, 1 with tenosynovitis, 1 with polymyalgia rheumatica, and three suspected of having RA whose progress was being followed. All non-RA patients who fulfilled the Yamasaki criteria satisfied the JRA criteria.

### Sensitivity and specificity of each diagnostic item

#### *ACR criteria*

The items of the ACR criteria showing more than 80% for both sensitivity and specificity were "swelling of three joint areas" and "symmetric swelling." The sensitivity of "morning stiffness of at least 1-h duration persisting for 6 weeks" was low at 35.6%. Radiographic changes of the hand were noted in 8.9% of cases, while rheumatoid nodules were not observed in any patient. The specificity of the rheumatoid factor was low at 73.3% (Table 1).

#### *Yamasaki criteria*

The items of the Yamasaki criteria showing more than 80% for both sensitivity and specificity were "swelling of three joint areas" and "symmetric swelling," which is in accordance with the ACR criteria. "Morning stiffness of at least 15 min duration persisting for 1 week" showed a sensitivity of 80% and a specificity of 75.6%. The specificity of "swelling of the hand and ankle joints persisting for at least 1 week" was low at 53.3% (Table 2).

#### *JRA criteria*

Among the JRA criteria, all five items except "rheumatoid nodules" showed sensitivities of more than 80% but specificities of less than 80%. In particular, "the presence or absence of morning stiffness" and "20mm or more of erythrocyte sedimentation rate or positive CRP" demonstrated low specificities of 55.6% and 48.9%, respectively (Table 3).

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## Discussion

An early diagnosis and prompt treatment can improve the outcome in rheumatoid arthritis. Although joint destruction may begin early in the course of RA, diagnosis and

**Table 1.** The American College of Rheumatology criteria 1987

	Sensitivity (%)	Specificity (%)
1. Morning stiffness	35.6	95.6
2. Arthritis of three or more joint areas	80.0	93.3
3. Arthritis of hands	88.9	73.3
4. Symmetric arthritis	86.7	84.4
5. Rheumatoid nodules	0.0	100
6. Serum rheumatoid factor	86.7	73.3
7. Radiographic changes	8.9	100

**Table 2.** Yamasaki diagnostic criteria for early rheumatoid arthritis

	Sensitivity (%)	Specificity (%)
1. Morning stiffness <sup>a</sup>	80.0	75.6
2. Arthritis of three or more joint areas <sup>b</sup>	80.0	86.7
3. Arthritis of hand, MCP, PIP, ankle, or MTP joints	91.1	53.3
4. Symmetric arthritis	88.9	84.4
5. Serum rheumatoid factor	86.7	73.3
6. Radiographic changes of hand or foot <sup>c</sup>	11.1	100

<sup>a</sup>Lasting at least 15 min before maximal improvement

<sup>b</sup>The 18 possible areas are right or left distal interphalangeal (DIP), proximal interphalangeal (PIP), metacarpophalangeal (MCP), wrist, elbow, shoulder, knee, ankle, and metatarsophalangeal (MTP) joints where the arthritis is a soft tissue swelling or fluid (not bony overgrowth alone)

<sup>c</sup>Spindle-shaped swelling of soft tissue, erosion, or unequivocal bony decalcification. For classification purposes, patients shall be said to have rheumatoid arthritis if they have satisfied at least four of these six criteria. Criteria 1–4 must have been present for at least 1 week

**Table 3.** The criteria of the Japan Rheumatism Association for early rheumatoid arthritis

	Sensitivity (%)	Specificity (%)
1. Tenderness or passive movement pain of three or more joints	80.0	77.8
2. Swelling of two or more joints	93.3	60.0
3. Morning stiffness <sup>a</sup>	84.4	55.6
4. Rheumatoid nodules	0	100
5. Erythrocyte sedimentation rate $\geq 20$ or CRP(+)	82.2	48.9
6. Rheumatoid factor	86.7	73.3

<sup>a</sup>Presence or absence

If patients have satisfied at least three of these six criteria, they should be observed carefully, and treated according to their symptoms

subsequent initiation of therapy are often delayed. There is often a considerable lag time between symptom onset and the diagnosis of RA. The ACR criteria appear to be most sensitive and specific and are the standard for RA, but these criteria do not perform well for early RA, and it has been suggested that they need to be revised for this condition.<sup>6–8</sup>

The JRA criteria for early RA showed a high sensitivity of 95.6% but a slightly low specificity of 77.8%. In contrast, the Yamasaki criteria provided favorable results, with a sensitivity and specificity of 88.9% and 93.3%, respectively.

Therefore, the Yamasaki criteria seem to be appropriate for diagnosing early RA, while the JRA criteria for early RA, showing a sensitivity of 95.6%, appear to be suitable for screening patients with early RA.

The results for each diagnostic item of articular findings were compared among the three sets of diagnostic criteria. With respect to the items “swelling of three joint areas” and “symmetric swelling,” the ACR criteria imposed a condition of a 6-week duration, while the Yamasaki criteria cut this requirement to 1 week. For these two items, the sensitivities and specificities of both the ACR and the Yamasaki criteria exceeded 80%. This result suggests that for “swelling of three joint areas” or “symmetric swelling,” an observation period of 6 weeks is not necessary in early RA, and an observation period of 1 week is sufficient.

Concerning the item “swelling of the wrist, metacarpophalangeal (MCP), and proximal interphalangeal (PIP) joints,” the ACR criteria set a condition of 6 weeks duration, while the Yamasaki criteria imposed a condition of 1 week duration while adding swelling of the ankle and MTP joints to the criteria. The sensitivity between the ACR criteria and the Yamasaki criteria of 88.9% and 91.1%, respectively, did not differ. However, the specificity of the Yamasaki criteria (53.3%) was lower than that of the ACR criteria (73.3%). This is because OA, gout, and other diseases sometimes induce joint swelling persisting for 1 week, and therefore with swelling of the hand and ankle joints, observations for a longer period seemed to be necessary even in early RA.

The item “morning stiffness” was compared among these sets of diagnostic criteria. The sensitivity of the ACR criteria, which specify stiffness for at least 1 h persisting for 6 weeks or more, was low at 35.6%, while the specificity of the JRA criteria questioning the presence or absence of stiffness was low at 55.6%. Comparatively few patients showed stiffness for at least 1 h persisting over 6 weeks or more, and as king about the presence or absence of stiffness was not objective. Nobunaga and Huruta<sup>9</sup> reported that the presence of certain types of stiffness of even a short duration was important during the diagnosis of early RA, suggesting that the condition of stiffness of at least 15 min duration persisting for 1 week in the Yamasaki criteria is appropriate. In this study, the sensitivity and specificity of “stiffness” in the Yamasaki criteria were 80.0% and 75.6%, respectively, which also indicates that “15 min” and “1 week” are suitable values.

In Japan, the positive rate for rheumatoid factors among RA patients was reported to be 60–80%.<sup>10</sup> In the present study, the rate was slightly higher at 86.7%, but this seemed to be because many comparatively severe cases were included.

The item of “CRP positivity or an erythrocyte sedimentation rate of 20 mm or more” in the JRA diagnostic criteria demonstrated a high sensitivity of 82.2% but a low specificity of 48.9%. Thus, this item requires close attention if it is to be used as a diagnostic criterion, despite being appropriate for screening.

For treatment of RA to be initiated during the early stage, an early diagnosis is necessary. The results of this

study demonstrated that the early diagnosis of RA is possible. However, such a diagnosis is insufficient in some cases. Therefore, when treatment is initiated during the early stage, we should administer appropriate treatment while closely following the patient.

When treatment for RA is initiated during the early stage of the disease, the Yamasaki criteria are considered to be relatively appropriate for the diagnosis. However, the item "swelling of the hand and ankle joints persisting for 1 week or more" in the Yamasaki criteria seems to require observation for a longer period, which warrants further detailed investigation. When identifying RA patients by screening during the early stage, a more sensitive JRA criteria seemed to be more suitable. We intend to take advantage of these two sets of diagnostic criteria and utilize them during treatment of early RA in the future.

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## References

1. Arnett FC, Edworthy SM, Bloch DA, McShane DJ, Fries JF, Cooper NS, et al. The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis. *Arthritis Rheum* 1988;31:315–24.
2. Yamasaki K. Preliminary diagnostic criteria for early rheumatoid arthritis (in Japanese). *Nihonijishinpo* 1988;No.3360:43–7.
3. Yamamoto S, Nobunaga T, Kashiwazaki S. Study on Japan Rheumatism Association diagnostic criteria for early rheumatoid arthritis. 1. Application of the American Rheumatism Association diagnostic criteria to Japanese patients with early rheumatoid arthritis (in Japanese). *Ryumachi* 1993;33:354–62.
4. Yamamoto S, Kashiwazaki S, Nobunaga T. Study on Japan Rheumatism Association diagnostic criteria for early rheumatoid arthritis. 2. Proposed diagnostic criteria for early rheumatoid arthritis (in Japanese). *Ryumachi* 1994;34:1013–8.
5. Pinals RS, Masi AT, Larsen RA. Preliminary criteria for clinical remission in rheumatoid arthritis. *Arthritis Rheum* 1981;24:1308–15.
6. Conaghan PG, Green MJ, Emery P. Established rheumatoid arthritis. *Baillieres Best Pract Res Clin Rheumatol* 1999;13:561–75.
7. Fleischmann RM. Early diagnosis and treatment of rheumatoid arthritis for improved outcomes: focus on etanercept, a new biologic response modifier. *Clin Ther* 1999;21:1429–42.
8. Chan KW, Felson DT, Yood RA, Walker AM. The lag time between onset of symptoms and diagnosis of rheumatoid arthritis. *Arthritis Rheum* 1994;37:814–20.
9. Nobunaga M, Huruta E. Clinical features of early rheumatoid arthritis (in Japanese). *Ryumachika* 1993;10:271–5.
10. Nishioka K. Diagnosis and treatment of rheumatoid arthritis in terms of a new concept of its etiology (in Japanese). *Nihonijishinpo* 1993;No.3629:7–10.