SPECIAL ARTICLE

PRELIMINARY CRITERIA FOR CLINICAL REMISSION IN RHEUMATOID ARTHRITIS

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A study was conducted to develop criteria for clinical remission in rheumatoid arthritis (RA). Data were provided by 35 rheumatologists on 175 RA patients considered to be in complete remission (with or without antirheumatic therapy) and 169 RA patients in partial remission or with active disease. Six criteria yielded optimal discrimination: morning stiffness absent or not exceeding 15 minutes, no fatigue, no joint pain by history, no joint tenderness, no joint or tendon sheath swelling, and no elevation of erythrocyte sedimentation rate. In this study sample, the presence of five or more of these criteria in an individual patient yielded 72% sensitivity for clinical remission and 100% specificity in discriminating RA patients with active disease. In a population sample, it is estimated that the overall accuracy of these criteria would be more than 90% in RA patients.

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Although there is general agreement that complete remission of disease activity may occur in rheumatoid arthritis (RA), either spontaneously or under the influence of medications (1,2), the characteristics of this state of remission have never been defined. The term "complete remission" implies the total absence of all articular and extraarticular inflammation and immunologic activity related to RA. Although this state may be achieved occasionally (3), remission is more likely to be incomplete, even under the influence of potent drugs and after long periods of freedom from symptoms. Short's prospective study on patients in apparent remission over a period of many years served to emphasize this point (4). The term "partial remission" might be used to describe reduced disease activity, below any arbitrary cutoff point that falls along a continuum approaching complete remission on the one extreme and active disease on the other. A definition of the gradations of partial remission might be viewed as part of the larger problem of quantitation of disease activity in RA, as set forth by McCarty (5).

A standardized definition of "complete clinical remission" could serve to dispel the vagueness and confusion that currently accompany the use of this term. Such a definition might next be applied to the study of the natural history of RA or to determine endpoints in therapeutic trials for this disease.

A subcommittee of the American Rheumatism Association (ARA) Committee on Diagnostic and Therapeutic Criteria was assigned the task of developing criteria for remission. The aim was to achieve uniformity in clinical application, using generally acceptable and convenient measurements, rather than to identify an absolute state of remission that could be documented only by extraordinary measures. The

Table 1. Stages of data reduction and analysis

1. Frequency distributions and means for each variable were determined in each entry group.
2. Univariate analysis was performed to detect intergroup differences.
3. Promising variables and appropriate cutoff points were selected for possible inclusion in criteria.
4. Multivariate analysis was performed using variables with best discriminating power.
5. Using discriminant functions as indices of sensitivity and specificity, efforts were made to reduce the number of variables included in criteria.
6. Weighting and exclusions were explored as instruments to improve sensitivity and specificity of the criteria.

subcommittee proposed preliminary criteria by consensus but recommended confirmation by a more representative prospective study. The present investigation was based upon information provided by a larger group of rheumatologists concerning the current and past clinical status of RA patients under their care, including those believed to be in complete remission and various states of activity.

PATIENTS AND METHODS

Study participants were 35 clinical rheumatologists. Each was asked to provide current clinical information on RA patients and to make a judgment regarding disease activity in four categories: 1) complete remission without treatment at present, 2) complete remission with ongoing treatment, 3) near or partial remission, or 4) active disease. Patients with juvenile rheumatoid arthritis, ankylosing spondylitis, Reiter's syndrome, or arthritis associated with either psoriasis or chronic inflammatory bowel disease were excluded.

A 6-page data collection form was completed in each case, including demographic information, past and present symptoms, laboratory data, explanations of radiographic changes, and the results of a detailed joint examination. After review for errors and omissions, data were transferred to computer coding forms as either dichotomous or continuous variables. Some of the latter (particularly laboratory results) were stratified so that each entry could be expressed in terms of steps above the normal range provided by the examiner.

Each variable was examined with the objective of selecting those that discriminated between the remission and nonremission groups. The stages of data reduction and analysis are presented in Table 1.

Chi-square analysis with Yates' correction and the Fisher exact test were used for comparing dichotomous variables, and the unpaired Student's *t*-test was employed for evaluating the significance of differences in means for continuous variables. The *sensitivity* of criteria for remission is defined as the proportion of patients in the complete remission entry category who satisfied remission criteria, while the *specificity* is the proportion of patients with partial remission or active disease who did not satisfy remission criteria.

RESULTS

Of the 344 patients entered, 175 were considered by their physicians to be in complete remission, either without (63) or with (112) concurrent treatment for RA. The two complete remission groups did not differ significantly in any respect and were, therefore, combined for most subsequent analyses. Of the remaining 169 patients, 93 were in partial remission and 76 had active disease. The initial goal of entering an equal number of patients in each category by each examiner was not attained, both because of variable levels of compliance and because of the difficulty of identifying patients in the category of complete remission without current treatment.

Demographic features and past clinical status. The female:male ratio was slightly less than 2:1, and 90% of the patients were white. The mean age of onset of RA was 43 years, and the mean disease duration at the time of this evaluation was 9 years. The entry groups did not differ significantly in these characteristics nor in indicators of past disease severity. Regarding the frequency of rheumatoid factor positivity in the past, the frequencies were somewhat higher in patients with active disease (87%) than for those in complete remission (74%) ($P = 0.06$), but maximum erythrocyte sedimentation rate (ESR) elevations did not differ. The frequency of bone erosion and joint space narrowing, determined radiographically, did not differ among the various entry groups. Past therapy with major antirheumatic drugs (gold, antimalarials, D-penicillamine, corticosteroids, cytotoxic agents) was generally similar for all groups, including patients in complete remission not currently receiving treatment. Only 33% of patients in the latter group had never been treated with any of the above listed agents.

Present clinical status (Table 2)

Rheumatic symptoms. Duration of morning stiffness was a highly discriminating variable. Only 18% of patients in complete remission had morning stiffness, compared with 96% of those with active disease. However, the best discrimination between groups was obtained at a cutoff point of 15 minutes duration of morning stiffness ($P < 0.0001$).

On the protocol forms, we requested information on severity of joint pain and fatigue (none, mild,

Table 2. Clinical variables among RA patient groups at entry to study

	Complete remission	Partial remission	Active disease
Symptoms			
Morning stiffness (%≤15 minutes)	96	55	13
Fatigue (% none)	87	60	12
Joint pain (% none)	83	33	1
Joint examination			
Tenderness/pain on motion (% none)	89	46	4
Soft tissue swelling (% none)	86	43	7
Limitation of motion (% none)	63	45	8
Tenosynovitis (% none)	95	78	67
Extraarticular manifestations (% positive)			
Rheumatoid nodules	24	30	45
Vasculitis	0	0	3
Pericarditis	0	0	0
Pleuritis	0	0	2
Episcleritis	2	0	3
Sjögren's syndrome	9	9	19
Splenomegaly	1	2	0
Raynaud's phenomenon	2	0	2
Neuropathy	1	0	5
Carpal tunnel syndrome	1	3	5
Lymphadenopathy	0	3	3
Fever	0	0	6
Weight loss	0	0	9
Myositis	0	0	5
Laboratory			
Rheumatoid factor (% negative)	70	51	19
ESR (% <30 females, <20 males)	77	59	18
Hematocrit (% >36 females, >42 males)	90	78	62
Radiography			
No abnormality	23	31	20
Erosion (% present)	61	56	64
Joint space narrowing (% present)	62	56	66
Ankylosis (% present)	1	0	0

moderate, severe). Differences among all three groups were highly significant ($P < 0.0001$). Only 3 patients in complete remission had more than mild pain, and 2 had more than mild fatigue.

Joint examination. The protocol form provided data on the number and distribution of affected joints showing tenderness or pain on motion, soft tissue swelling, and limitation of motion. For the first two variables, highly significant intergroup differences were demonstrated ($P < 0.0001$), but limitation of motion was similar in both complete and partial remission patients. Rather surprisingly, soft tissue swelling, usually of minimal degree, was reported by 16 examining physicians in 24 patients in complete remission. Comparing these patients to the remainder of the group, one finds few differences in other variables. Patients in complete remission with soft tissue swelling had less joint pain ($P = 0.03$), but higher ESR ($P = 0.02$) than those without swelling. All had improved markedly in every respect compared with their former clinical status. Significant differences in frequency of tenosynovitis were found between the entry groups. When tenosynovitis was present, most patients had swelling in tendon sheaths, and all except 1 of these had simultaneous joint swelling.

Extraarticular manifestations. As expected, more evidence of systemic illness was found in patients with active disease. However, there were no significant differences between the complete and partial remission groups. Rheumatoid nodules and Sjögren's syndrome were frequently present in patients in complete remission. Fever, recent weight loss, and myositis were present only in patients with active disease ($P < 0.05$). Other systemic features, such as vasculitis, pleuritis, and pericarditis were not found in remission patients and were infrequent in individuals with active disease.

Laboratory studies. Serum rheumatoid factor

Table 3. Percent of patients on various forms of drug treatment at entry to study and at any time in past

Drug treatments	Complete remission: Without current treatment (n = 63)		Complete remission: With current treatment (n = 112)		Partial remission (n = 93)		Active disease (n = 76)		*P* values of comparisons (entry/past)*		
	Entry	Past	Entry	Past	Entry	Past	Entry	Past	CR vs PR	CR vs AD	PR vs AD
Gold	0	49	61	79	49	69	28	54	NS/NS	§/§	§/NS
Corticosteroid	0	27	17	42	16	26	42	53	NS/†	§/NS	§/§
Antimalarial	0	24	9	29	6	24	14	25	NS/NS	NS/NS	NS/NS
Penicillamine	0	0	4	4	5	6	12	17	NS/NS	NS/‡	NS/NS
Azathioprine	0	19	2	7	2	6	1	4	NS/NS	NS/NS	NS/NS
NSAID¶	0	86	56	95	82	95	86	93	§/NS	§/NS	NS/NS

* CR = complete remission with current treatment; PR = partial remission; AD = active disease. NS = not significant.
† = $P < 0.05$.
‡ = $P < 0.01$.
§ = $P < 0.001$.
¶ NSAID = nonsteroidal antiinflammatory drugs, including salicylates.

was negative significantly more often in the complete remission group at entry to study, but was found in 30% of these patients, diminishing its discriminating value. Titers were also lower in patients in complete remission, but 22% had high titers (greater than three tube dilutions above the upper limit of normal for the laboratory performing the test). Comparing entry with past rheumatoid factor positivity in the complete remission group, there is an impressive difference: 74% of patients had a positive test at some time in the past, 56% with high titers. This frequency bears a close resemblance to the active disease group on entry.

ESR analysis was confounded by the fact that three different methods were used. The Westergren method was used in 90%, Wintrobe in 6%, and Rourke-Ernstene in 4%. Raw (uncorrected) values by the Wintrobe method were entered along with Westergren values with the realization that those in the higher Wintrobe range would be falsely low on the Westergren scale. However, these results would be less pertinent to the remission issue than values in the lower range. Rourke-Ernstene values were also included after multiplication by a factor of 100. The inclusion or omission of ESR values obtained by methods other than Westergren did not alter the distribution of values in each group, largely due to the preponderance of Westergren determinations. In the complete remission group, 16% of all patients had ESRs greater than 30 mm/hour (10% of males and 21% of females). Although 38% of patients in partial remission had an ESR over 30 mm/hour, the two remission groups did not differ significantly from each other, and both were different from the active disease group ($P < 0.0001$). The ESR levels yielding optimal separation of the remission groups from the active disease group were 20 mm/hour for males and 30 mm/hour for females.

In regard to anemia, there were no differences between the remission groups, but anemia was more frequent in patients with active disease when compared with those in complete remission. These differences were more pronounced among males ($P < 0.0001$) than females ($P < 0.03$).

Radiographs. New radiographs were not required in the study because of the costs involved and the likelihood that disease activity would not be adequately reflected by radiographs at a single point in time. This information was intended to be used as an index of disease severity. No information was available for 37 patients, and for many others, the radiographs were not recent enough to reflect current status. Considering these limitations, none of the groups differed from one another on individual or combined total joint findings. These films served mainly to characterize the RA patient population as one in which more than two-thirds of the patients had destructive rheumatoid arthritis irrespective of entry grouping.

Drug treatment. By definition, patients in group 1 were not receiving antirheumatic medication. Analysis of current treatment in the remaining entry groups (Table 3) revealed that fewer patients in complete remission were taking salicylates and other nonsteroidal antiinflammatory drugs; gold therapy was currently being administered to 61% and corticosteroids to 17% of these patients. More than half of the patients in

Table 4. Proposed criteria* for complete clinical remission in rheumatoid arthritis†

Five or more of the following requirements‡ must be fulfilled for at least 2 consecutive months:§

1. Duration of morning stiffness not exceeding 15 minutes
2. No fatigue
3. No joint pain (by history)
4. No joint tenderness or pain on motion
5. No soft tissue swelling in joints or tendon sheaths
6. Erythrocyte sedimentation rate (Westergren method) less than 30 mm/hour for a female or 20 mm/hour for a male

* These criteria are intended to describe either spontaneous remission or a state of drug-induced disease suppression, which simulates spontaneous remission.

† To be considered for this designation a patient must have met the ARA criteria for definite or classic rheumatoid arthritis at some time in the past.

‡ No alternative explanations may be invoked to account for the failure to meet a particular requirement. For instance, in the presence of knee pain, which might be related to degenerative arthritis, a point for "no joint pain" may not be awarded.

§ Exclusions: Clinical manifestations of active vasculitis, pericarditis, pleuritis or myositis, and unexplained recent weight loss or fever attributable to rheumatoid arthritis will prohibit a designation of complete clinical remission.

complete and partial remission on corticosteroid therapy were receiving a dose equivalent to or less than 5 mg of prednisone daily. A separate analysis was performed to compare other variables and patient characteristics of patients in complete remission receiving or not receiving corticosteroids, but no significant differences were found.

Multivariate analysis. Six variables showing clearly significant differences between the complete remission and active disease groups were selected for criteria development (Table 4). Further additions (e.g., hematocrit and rheumatoid nodules) resulted in a decrease in sensitivity and were thus discarded. We tried to weight variables that appeared to be better discriminators, by using relative weights of 2:1 and 3:1 and to determine sensitivity and specificity for each combination. With equal weighting of the six variables, essentially the same results were obtained as with numerous variations in weighting and cutoff levels. The use of absolute exclusions in addition to a point-award format was investigated in detail. Criteria variables themselves were not useful for this purpose. For example, an absolute exclusion for the presence of soft tissue swelling of joints reduced discriminating power severely. Extraarticular manifestations, which occurred with significantly different frequencies in the remission and active disease groups, were tested as exclusion variables, but all failed to alter the discriminating power of the basic criteria sets.

In the preliminary consensus criteria proposed prior to this study, separate categories were used for patients with or without residual joint damage in recognition of the possibility that RA patients with deformity and destruction might not attain the same level of remission as those without residual changes. Using the data on our protocol forms, this distinction could be studied by separate consideration of patients on the basis of radiologic change (erosion or joint space narrowing) and physical examination (limitation of joint motion). Only 18% of all patients and 23% of patients in complete remission had no evidence of residual joint damage. In the complete remission group, there was a partial correlation between the number of limited joints and the criteria point score ($r = -0.44$), but point score was not significantly different in patients with and without residual damage, and a point requirement modifed on this basis failed to improve sensitivity or specificity.

Data on the duration of remission at the time of entry were available for only 117 patients (67%) in the complete remission group. The mean duration was 16 months with a range from less than 1 month to 5 years. Duration of less than 2 months was found in 10%, less than 4 months in 25%, and less than 1 year in 59%.

Of all the criteria sets tested, the six variables shown in Table 4 had the virtue of greatest simplicity. Their discriminating power can be exceeded only at the price of allowing credit for findings that are manifestations of disease activity, and even then the gain is minimal. Some concessions in this direction have been made by allowing 15 minutes of morning stiffness and slight elevations of ESR, both of which enhanced the performance of the criteria. The former may be justified by reports that brief periods of morning stiffness are common in individuals who do not have rheumatoid arthritis (6,7). The latter takes into account the variations of ESR with age in normal individuals and avoids an elaborate stratification of age-related normal values.

A few additional criteria requirements were deemed appropriate, even though they did not enhance discrimination among the study groups. Since swelling of tendon sheaths was relatively infrequent in complete remission patients, it was combined with joint swelling on the basis that both are expressions of the same pathogenetic process and that their differentiation is sometimes difficult. Certain systemic manifestations that did not occur in complete remission patients were used as exclusions for remission status, even though their frequencies in the other groups were too low to have a statistical impact.

Sensitivity and specificity of the proposed crite-

Table 5. Sensitivity, specificity, and percent of patients correctly classified according to different numbers of points required to satisfy clinical remission criteria

Comparison group and performance statistic	Number of points required to satisfy clinical remission criteria			
	3	4	5*	6
Partial remission only				
Sensitivity	97	90	72	44
Specificity	43	69	92	99
Percent correct†	80	83	78	62
Active disease only				
Sensitivity	97	90	72	44
Specificity	96	100	100	100
Percent correct	97	93	80	61
Combined comparison groups				
Sensitivity	97	90	72	44
Specificity	68	84	96	99
Percent correct	84	87	83‡	70

* Proposed criteria require five points or greater.
† Applies only to the numbers and proportions of patients included in this study with clinical remission and comparison groups.
‡ Percent correct estimated to be 91 if applied to an RA patient population with 20% in clinical remission, instead of the 51% (175 of 344) found in this patient sample.

ria were analyzed at different levels of required points (Table 5). If four points were required to satisfy clinical remission criteria, sensitivity would be 90%, but specificity would be only 69% against partial remission patients, although 100% against those with active disease. With five points required, these criteria have a sensitivity of 72% and a specificity of 92% against patients in partial remission. If one considers correct classification of remission patients at different levels of points required, the percent would be slightly higher with four (87.2%) than with five points (83.2%) when based upon all patients entered into this study. However, this statistic depends upon the number or proportion of patients in each category. In our study, the 175 remission patients constituted 51% of the total 344 patients, which is advantageous for statistical discrimination of remission and nonremission groups. However, this proportion is not necessarily representative of the population to which remission criteria will be applied. If one assumes that remission patients will constitute as many as one-fifth (20%) of RA patients, then the correct remission classification will be 85% with four points required and 91% with five points required. These calculations are based upon the respective sensitivity and specificity figures shown in Table 5 for all nonremission patients at each point level.

Information on the duration of remission was available on two-thirds of complete remission patients. In these patients, the sensitivity of the criteria could be evaluated according to varying durations of remission. The overall accuracy of the criteria did not change meaningfully regardless of whether duration was included, and a period of 2 months was chosen to satisfy criteria.

The distribution of remission points within each entry group is shown in Table 6. A sharp decrease in the number of remission points satisfied by partial remission patients is seen between four (23% of patients) and five (7% of patients).

DISCUSSION

A major obstacle to developing criteria for remission in rheumatoid arthritis is the difficulty in ascertaining the absence of inflammation by methods that are reliable and also convenient in clinical settings. Biopsy of several previously involved joints is unlikely to be acceptable to patients and their physicians. Abnormalities in serum proteins (8) and radionuclide scans (9) may persist when clinically obvious synovitis is absent, suggesting that these alterations may represent changes other than active rheumatoid inflammation. There is some evidence that disease which appears to be inactive clinically may progress radiologically, leading to the conclusion that a state of remission must be confirmed retrospectively by absence of radiologic progression (10). However, this approach is limited by the costs of repeated radio-

Table 6. Distribution of remission points within entry groups (expressed as % of patients at each point level)

Number of remission points	Complete remission		Partial remission (n = 93)	Active disease (n = 76)
	Without current treatment (n = 63)	With current treatment (n = 112)		
6	52	40	1	0
5	27	28	7	0
4	16	20	23	0
3	5	8	26	4
2	0	4	18	7
1	0	0	19	26
0	0	0	5	62
Mean number of points (±SD)	5.3 (±0.9)	4.9 (±1.1)	2.7 (±1.4)	0.5 (±0.8)

graphic studies, the variability of technique and interpretation, and the uncertainty that progressive change is a function of synovitis rather than secondary degeneration.

Thus, there are no generally accepted standards for calibration of clinical variables which must be used in developing criteria for remission. Our proposed criteria employ clinical information, which can be ascertained at the bedside or in the physician's office, to define remission as it is used in common speech. The goals are uniformity and convenience to encourage general use of the criteria.

In addition to the spectrum of disease activity, the concept of remission may also include a time dimension, varying from a few days to indefinitely extended periods. Selection of a required disease-free interval would likely be arbitrary. A remission of several years duration may be regarded with great confidence, but from a functional point of view, such criteria may be unusable. However, if a day or a week is sufficient for the designation of remission, the term would circumscribe transitory events, which may not be indicative of a major trend in the course of RA. Patients in remission for only brief periods were not entered into the study, indicating that the participating physicians did not think that such patients exemplified their definition of the term. As a result of this study, a period of 2 months in remission status was chosen because 90% of the remission patients satisfied this criterion.

Although inclusion of patients in spontaneous remission was actively solicited, we only received information on a few such patients. This may indicate that natural remissions are rare, or that these patients visit rheumatologists too infrequently to be included in a study of this type. In the entry category of complete remission without current treatment, only 21 patients had never received "remission-inducing" drugs. In the past, these patients were not substantially different in clinical characteristics and course from those who were believed to be in remission while still under treatment. Many rheumatologists have been unwilling to consider the term remission to be appropriate for patients still receiving or under the influence of previous therapy with potent therapeutic agents. For this reason, a qualification has been included, noting that the proposed criteria are also intended to describe a state of drug-induced disease suppression that simulates remission. This state may have only a superficial resemblance to natural remission, with entirely different basic immunologic features, but it is precisely these overt clinical appearances that we are attempting to delineate.

Substantial variation appears to exist in the concept of remission within the group of participating rheumatologists. Some define remission in a rigidly exclusive manner, insisting on a total absence of all features that might indicate disease activity. Others view the remission state in a relative way and are willing to apply the designation if a patient has improved markedly, has essentially no symptoms, and has achieved the lowest possible level of objective findings for his or her particular case. Thus, patients entered in the partial remission group by a rheumatologist with the "absolutist" viewpoint might be almost identical with patients assigned to the complete remission group by a "relativist." For example, almost half of the participants entered 1 or more complete remis-

sion patients in whom soft tissue swelling was present. To confirm this surprising finding, more information was solicited on a supplementary questionnaire. The original response was confirmed in every case, with a variety of qualifications. Other rheumatologists objected passionately to the notion that a patient with any articular swelling might be in complete remission. The proposed criteria skirt the issue by allowing an alternative pathway to remission status; thus, a patient with joint swelling would have to meet all of the remaining five remission requirements.

In this study, we have resisted the temptation to define the transitional group (partial remission), although this might be accomplished on the basis of requiring three or four remission points rather than five. The issue of staging and defining levels of disease activity is an important one, which has not been addressed in this study. Other approaches to defining these levels would be more appropriate than those employed in this study.

We would like to emphasize that these proposed criteria are not based on a population sample of RA patients and that their modification in the future is both expected and encouraged. Further experience, particularly in prospective studies, will be required to determine their value and applicability in various groups of patients.

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