Dear Editors at Journal of Rheumatology,

Enclosed is a full-length manuscript of our study titled: Association between patient perception of disease status and different components of the Minimal Disease Activity (MDA) criteria in psoriatic arthritis. The final manuscript has been reviewed and approved by all the authors, and ethical approval was obtained in each country or centre. All participants gave informed consent to take part in the ReFlaP study. We have given the necessary attention to ensure the integrity of the work, and we agree to bear the applicable publication charges if the manuscript is accepted for publication.

We thank you for the time and opportunity.

Kind regards,

The authors of the submitted work

Running head: MDA components in PsA

Association between patient perception of disease status and different components of the Minimal Disease Activity (MDA) criteria in psoriatic arthritis

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Abstract

Objective: The aim of this analysis was to evaluate the relationship between the criteria met of the Minimal Disease Activity (MDA) score for psoriatic arthritis (PsA) and patient-perceived disease status.

Methods: We analysed data from the ReFlaP study (NCT03119805), a cross-sectional international study of adult patients with PsA. Patients self-reported if they felt their PsA was in remission (REM), low disease activity (LDA) or neither. The relationship between patient-reported status and MDA domains met was analysed using point biserial correlation, chi-square test (X^2), odds ratio, and specificity.

Results: 88.4% of study patients who met MDA reported good disease status (REM/LDA). Pain was the most commonly missed domain for these patients. A moderate to strong correlation was found between meeting more MDA domains and patient-reported good status irrespective of domain missed. On individual domain testing, MDA state and patient-reported REM/LDA were significantly associated irrespective of domain missed with the exception of enthesitis. Specificity of the MDA score irrespective of domain missed was above 90%. The odds of MDA patients reporting poor disease status was significant only for when pain < 1 was the unmet domain. This significance was not supported by sensitivity analysis.

Conclusion: This study suggests strong agreement between MDA status and patient-reported good status irrespective of domain missed. Pain < 1 or 2 on a 0-10 numerical rating scale was the hardest domain to meet. The high specificity regardless of the unmet domain suggests patients who feel their disease is active are minimally misclassified by the score.

Introduction

Psoriatic arthritis (PsA) is a common form of inflammatory arthritis affecting about 1 in 4 individuals with skin psoriasis[1]. Internationally standardised management of PsA follows a treat-to-target (T2T) approach where the treatment goal is remission, with low disease activity used as an acceptable target for many patients[2,3]. Part of the challenge in PsA management is its heterogeneous clinical manifestations involving joints, entheses and spine as well as the skin and/or nails[4]. Current national and international treatment recommendations, including those developed by the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) and the European League Against Rheumatism (EULAR) , advocate optimizing treatment to achieve disease control in all active domains of the disease[3,5].

The Minimal Disease Activity (MDA) criteria were developed as a disease activity target in PsA and are one of the two instruments recommended in the international recommendations for T2T[2]. MDA differs from other scoring tools in PsA in its multidimensionality, with 7 measures assessing both arthritic and extra-arthritic components, including entheses, skin disease and overall patient function[6]. Achieving at least 5 of the 7 measures is defined as achieving ‘minimal disease activity’ (MDA), and achieving all 7 measures is defined as achieving ‘very low disease activity’ (VLDA), or clinical remission.

The European Medicines Agency (EMA) published a letter of support for the MDA criteria as a primary endpoint in drug development in interventional and observational studies[7]. However additional data on the properties of the score were requested for final validation.

The objective of this study was to assess whether “minimal disease activity” as measured by the MDA criteria was perceived as a good disease state, i.e. low disease activity or remission, by the patient and whether this was consistently true regardless of which MDA domains were unmet.

Methods

Study population

This was a post-hoc analysis of data from the Remission/Flare in PsA (ReFlaP) study, a cross-sectional, observational study of adult patients from 21 centres in 14 countries who had PsA for >2 years (NCT03119805). The original study took place between June 2017 and August 2018, and its objective was to assess different definitions of remission/low disease activity in PsA[8].

Data collection

In the ReFlaP study, patient demographics, clinical characteristics and disease characteristics including the 7 domains of the MDA score (shown in TABLE 1) were collected during an initial and follow-up clinical encounter. In this analysis only baseline data from the initial encounter was used.

Physician-reported measures

Physicians completed physical examinations to record swollen joint count (SJC), tender joint count (TJC), tender entheseal points (using the Leeds Enthesitis Index) and body surface area (BSA) of psoriasis. Physicians categorized BSA into one of 4 categories: 1) No psoriasis lesions on the skin, 2) Limited psoriasis: body surface 1-5%, 3) Extensive psoriasis: body surface 6-20%, 4) Very extensive psoriasis: body surface >20%.

Patient-reported measures

Patients completed a Health Assessment Questionnaire (HAQ) at each visit, and a composite score between 0-3 was calculated from their responses. Patients also completed a patient global assessment (PGA) by indicating their disease activity on a 0-10 visual analogue scale with higher values indicating worse severity in response to ‘How active was your rheumatic disease on average during the last week?’ Patients reported pain similarly by rating their pain on a 0-10 visual analogue

scale in response to ‘How would you describe the overall level of pain (related to psoriatic arthritis) you have had during the last week?’

In the MDA score, pain VAS cut-off is ≤15mm. Since in the ReFlaP study patients indicated their level of pain on a 0-10 rating scale, either a cut-off of ≤1 or ≤2 can be used. For the main analysis of this study a cut-off of ≤1 was used as the more strict definition. The less stringent cut-off of ≤2 was used for sensitivity analysis.

The PGA VAS cut-off in the MDA score is ≤20mm. Here on a 0-10 rating scale the cut off of ≤2 was used.

Patients were asked to report whether or not they believed their PsA was in remission (REM) or low disease activity (LDA) by answering yes or no to the questions ‘At this time, is your psoriatic arthritis in remission, if that means you feel your disease is as good as gone?’ and ‘At this time, are you in low disease activity, if this means your disease is in low activity but it's not as good as gone?’ respectively. These questions were developed for this study with the help of patient research partners[8].

Statistical analysis

All patients meeting inclusion criteria with complete data on patient-reported REM/LDA and MDA criteria were analysed. Patients who achieved MDA by meeting 5 or 6 criteria were in MDA state. Patients who met all 7 criteria were in VLDA state. This division was kept in order to isolate patients meeting MDA state who missed at least one domain. Patient-reported REM and LDA were combined in this study as REM/LDA to reflect patient satisfaction with disease control (i.e. good disease state.) Descriptive statistics including frequencies, means and SDs were used to summarise patient demographics, baseline clinical characteristics, and prevalences of MDA criteria met.

All data was analysed using SPSS, version 28 (IBM SPSS Statistics for Windows, version 28.0). All relevant statistical tests were two sided, and p <0.05 was considered statistically significant.

The relationship between the number of MDA criteria met and patient-reported REM/LDA was analysed using point-biserial correlation. A significant positive correlation value indicated meeting more criteria correlates positively with patients reporting good disease status.

The association between meeting MDA state and self-reporting REM/LDA was assessed using chi-square test (X^2). The chi-square value indicated the magnitude of difference between the observed association and the predicted (i.e. no association) with $p < 0.05$ considered a significant association.

The odds ratio of patients in MDA state not reporting REM/LDA was measured. A significant odds ratio suggested missing a criteria had a negative effect on patient-reported good disease status. Lastly, to assess MDA score performance for when each domain was missed, specificity and positive predictive value (PPV) of the MDA score were calculated against patient-reported REM/LDA as the reference for disease control.

For point-biserial correlation, chi square test, and specificity/PPV analysis we analysed subgroups containing all patients who missed each of the 7 MDA domains. For example, all patients in the study who missed TJC +/- other domains were analysed as a group where TJC domain was missed. This was done to allow us to observe for differences in patient-reported disease state depending on which domain was missed. For odds ratios, subgroups of patients missing each of the 7 domains were similarly analysed; however patients not in MDA state were excluded as they were not relevant to the analysis.

Results

Patient demographics and clinical characteristics

Of the 466 patients enrolled in the original ReFlaP study, 52 were excluded from this analysis for not meeting inclusion criteria (n=12) or for missing data (n=40), leaving a total of 414 patients for analysis.

Demographic and clinical characteristics of the study sample according to their self-reported disease status are described in TABLE 2.

Frequencies of MDA state, VLDA state and patient-reported REM/LDA

Of the 414 patients, 174 (42.0%) met at least 5 MDA criteria; 60 met 5 only, 61 met 6 criteria, and 53 met all 7 criteria (i.e. VLDA). 88.4% of the 121 patients who met 5 or 6 criteria (i.e. MDA state) reported REM/LDA (n=107). 96.2% of VLDA patients reported REM/LDA.

Domains most commonly missed for all MDA patients

Pain was the least met domain for all patients in MDA state (85 patients, or 70.2%), followed by PGA (40 patients, 33.1%). Even when a pain VAS cut-off of ≤2 was used, it remained the most frequently missed domain with 48 patients (44.9%) in MDA state missing the domain. The range of pain VAS values for patients in MDA state who missed this domain was 2 to 8 and mean pain was 3.3. Of the 4 MDA patients scoring a high pain score of 7 and 8, 2 reported REM/LDA.

Domains missed for MDA patients self-reporting good versus bad disease state

For both the 107 MDA patients reporting REM/LDA and the 14 MDA patients reporting poor disease state, pain was the least met domain as well (67.3% and 85.7% respectively.) FIGURE A compares the percentages of MDA domains missed for patients reporting good disease status versus poor disease status.

Domains missed for patients reporting REM/LDA but not meeting MDA state

Frequencies of domains missed was also examined for the 122 patients who did not meet MDA state but felt their disease state to be low or in remission. Similarly to other patient categories, pain was the most commonly missed domain (n=118, 96.7%) followed by PGA (n=99, 81.1%). Entheses was the least missed. Supplementary Figure A shows percentages of missed domains for these patients.

Correlation between MDA and patient-reported status

There was a moderate to strong positive correlation ($p < .05$) between meeting more MDA criteria and patient-reported REM/LDA for all patients and for each subgroup of patients missing each of the 7 domains (TABLE 3). As patients meeting only 5 criteria most commonly missed the combination of pain and PGA, point-biserial correlation was run for patients missing this combination as well, yielding a strong positive correlation. In other words, meeting more MDA criteria was positively correlated with patient reporting good disease status even when patients did not achieve both pain and PGA domains.

There was a significant association between meeting MDA state and patient-reported REM/LDA for each subgroup of patients missing one of the MDA domains with the exception of those who missed entheses. In other words, meeting MDA state is significantly associated with patients self-reporting good disease state in all combinations of criteria met except for when entheses was the unmet criteria. This significance was also found for patients missing both pain and PGA (TABLE 4). In the sensitivity analysis when pain ≤2 cut-off was used, the null hypothesis was similarly rejected for all cases except when entheses was missed.

Specificity and PPV

Specificity reflects the percentage of patients self-reporting lack of disease control who were classified as not meeting MDA state. The overall specificity of the MDA score was 88.1%. Specificity of the MDA score for when each individual domain was missed, and in addition for when the combination of PGA and pain was not met, remained above 90% (TABLE 4). This was similarly true in the sensitivity analysis for when a pain VAS cut-off of ≤2 was used.

The PPV indicates the percentage of patients meeting MDA who felt their disease was under control. PPV for the MDA score was 90.8%. It was calculated to be above 80% for all criteria except entheses (50.0%). Only 2 patients in MDA state missed the entheses domain, and one of them reported poor disease control.

Odds ratios

The odds ratios of patients in MDA state self-reporting active disease overall and for each subgroup missing a specific domain are shown in FIGURE B. When MDA was met with pain domain as the unmet domain, the odds ratio of self-reported active disease was 3.53 [95% CI 1.09, 11.43 with p = 0.035]. In the sensitivity analysis using a pain VAS cut-off of ≤2, the odds ratio did not meet statistical significance (1.83 [95% CI 0.63, 5.34 with p = 0.296]). For each of the other 6 domains, the odds ratio of patients in MDA state self-reporting active disease was not significant.

Discussion

While the frequencies of individual MDA domains met by PsA patients have been previously studied[9-11], and Gorlier et al. assessed patient-reported good disease control overall against MDA status in the ReFlaP study[8], to the best of our knowledge this is the first analysis assessing whether good disease control was reported as such by patients in MDA state irrespective of which MDA domains were missed in a large, multi-national study.

A majority (88.4%) of patients in MDA state in this study reported their disease was under control. In addition, a strong positive correlation was found between number of MDA criteria met and patient-reported REM/LDA for all patients as well as for each category of patients missing one of the 7 domains. In other words, patients were more likely to report an acceptable disease state when meeting more criteria regardless of which one was missed. We also found a significant relationship between meeting MDA and self-reporting remission or low disease status for each category of patients missing one of the criteria, with the exception of entheses. The inability to reject the null hypothesis for the category of patients missing entheses is most likely due to the fact that a very small number of patients in MDA state had active enthesitis (n=2). This finding is similar to findings of other papers in the literature where entheses is the least active domain in controlled PsA[9,12].

The positive correlation between meeting more MDA criteria and patient-reported good status further suggests a distinction between attaining MDA versus VLDA. Aiming to meet all 7 criteria (VLDA) is clinically better as it correlates with increased patient-defined controlled disease state, and as shown in an RCT by Coates et al, it is an attainable target for patients[13]. The consistently high specificity of the MDA score above 90% regardless of which domain of the MDA score is missed indicates minimal mis-classification of patients as having well-controlled disease. This result is highly relevant to clinical practice where misclassifying PsA patients with active disease as in remission could lead to joint damage and disability.

There was no increased odds of patients in MDA state reporting poor disease status when missing a domain, with the exception of pain. However, all odds ratios calculated including that of pain had wide confidence intervals, greatly limiting our certainty of true effect size. The increased odds of patient reporting poor status when missing pain was not supported by our sensitivity analysis when using the less stringent pain VAS cut-off of ≤2. Future OR studies using large sample sizes and a 0-100 analogue scale for pain VAS would help dispel the uncertainty of our OR findings.

We did not analyse the effects of all possible combinations of 2 missed criteria for patients meeting 5 criteria. Categorising patients in MDA state into every combination of 5 criteria would have resulted in 21 groups of very small samples (with 11 of these combinations having 0 patients.) Analysing these sub-groups who have given very low-powered, unworkable results. Instead, we ran statistical tests for missing domains individually as well as for the most common missed combination, pain and PGA, which provided useful insight into the fact that even the combination of the most difficult to meet domains (both patient-reported outcomes) was not associated with a decreased frequency of patient-reported REM/LDA for patients in MDA state.

As noted in our frequency analysis, pain, a patient-reported outcome, proved to be the most difficult domain to meet for patients in all disease states, followed by PGA, another patient-reported outcome. This included those who self-reported REM/LDA but did not meet MDA. The high rates of

reported pain overall likely reflects the challenge of attaining a low pain VAS score in general amongst PsA patients, a finding cited in a number of studies[14-16], as well as in our systematic literature review[17]. Residual pain is a well-recognised phenomenon in chronic autoimmune diseases including PsA[18]. While classically pain was attributed to a nociceptive cause, i.e. pain experienced from activated peripheral nerve fibres as a result of disease-induced tissue inflammation, it is now recognised that PsA pain is more complex and can be attributed to noninflammatory mechanisms[19]. In addition, there is significant overlap between chronic arthritis and pain syndromes such as fibromyalgia. A systematic review by Duffield et al. speaks more to this, estimating the prevalence of fibromyalgia in PsA patients across all included studies to be 18%[20].

The reduced precision in several of our analyses, including ORs and specificity/PPV analyses, stems principally from the fact that we dealt with small sample sizes within our contingency tables. As noted in our frequency analysis, only 14, or 11.6% of patients in MDA state overall reported poor status; in other words, the small values in the contingency table are a reflection of the fact that there was strong agreement between patients meeting MDA and self-reporting good disease status.

In summary, our analyses add to the growing body of evidence demonstrating strong agreement between meeting MDA state and patient-reported good disease status irrespective of which domain is unmet. Our correlation analysis demonstrated meeting more criteria is better in terms of patient perception of their disease state. This is clinically relevant as, in line with OMERACT principles and as acknowledged in the EMA letter of support, patient perspective is essential for defining acceptable disease states as treatment targets in PsA[21]. Future studies using more comprehensive measures of patient perception of their disease and comparing all combinations of MDA state can give greater insight into the relationship between MDA and patient experience.

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Figure legends

TABLE 1: VAS visual analogue scale; HAQ health assessment questionnaire; BSA body surface area

FIGURE A: TJC tender joint count, SJC swollen joint count, PGA patient global assessment, HAQ health assessment questionnaire, BSA body surface area

FIGURE B: OR (LCI - UCI; *p-value*): Pain and PGA 0.50 (0.16 - 1.53; *0.22*), BSA 2.34 (0.46 - 11.96; *0.30*), Entheses 10.53 (0.63 - 177.07; *0.10*), HAQ 0.25 (0.01 - 4.39; *0.34*), Pain 3.53 (1.09 - 11.43; *0.04*), PGA 1.61 (0.52 - 4.94; *0.41*), SJC 0.99 (0.12 - 8.30; *0.99*), TJC 0.39 (0.02 - 6.95; *0.52*).
TJC tender joint count, SJC swollen joint count, PGA patient global assessment, HAQ health assessment questionnaire, BSA body surface area, LCI lower confidence interval, UCI upper confidence interval

TABLE 3: TJC tender joint count, SJC swollen joint count, PGA patient global assessment, HAQ health assessment questionnaire, BSA body surface area
*Each subgroup consists of patients missing specified domain(s) with or without other domains

TABLE 4: TJC tender joint count, SJC swollen joint count, PGA patient global assessment, HAQ health assessment questionnaire, BSA body surface area
*Each subgroup consists of patients missing specified domain(s) with or without other domains

SUPPLEMENTAL FIGURE A: TJC tender joint count, SJC swollen joint count, PGA patient global assessment, HAQ health assessment questionnaire, BSA body surface area

Tables and Figures

TABLE 1

MDA criteria

1	Tender joint count ≤1/68
2	Swollen joint count ≤1/66
3	Patient global VAS ≤20
4	Pain VAS ≤15
5	HAQ ≤0.5
6	Enthesitis count ≤1
7	Psoriasis BSA ≤3%

TABLE 2

Patient demographics and clinical and disease characteristics

	All (n=414)	Patients in self-reported REM/LDA (n=280)	Patients in other disease states (n=134)
Male, n (%)	208 (50.2)	156 (55.7)	52 (38.8)
Mean age, years (SD)	52.3 (12.6)	52.9 (12.7)	51.0 (12.3)
Mean PsA duration, years (SD)	10.3 (8.1)	10.5 (8.2)	10.5 (8.2)
Mean level of schooling, years (SD)	12.9 (3.5)	12.9 (3.5)	12.8 (3.5)
Paid work, n (%)	232 (56)	161 (57.5)	71 (53)
Current smoking, n (%)	71 (17.1)	39 (13.9)	32 (23.9)
Conventional synthetic DMARD intake, n (%)	245 (59.2)	167 (59.6)	78 (58.2)
Biological DMARD intake, n (%)	232 (56)	165 (58.9)	67 (50)
Oral glucocorticoids, n (%)	65 (15.7)	34 (12.1)	31 (23.1)
Number of comorbidities, mean (SD)	0.7 (1.2)	0.7 (1.3)	0.7 (1.0)
Body surface area of psoriasis >/=5%, n (%)	57 (13.8)	30 (10.7)	27 (20.1)
Tender entheseal points, LEI mean (SD)	0.6 (1.3)	0.3 (1)	1.1 (1.7)
Tender joint count (0-68), mean (SD)	4.5 (9.0)	2.8 (7.1)	8.0 (11.3)
Swollen joint count (0-66), mean (SD)	2.0 (6.4)	1.2 (4.7)	3.7 (8.7)
Patient's assessment of pain (0-10), mean (SD)	4.0 (2.8)	3 (2.4)	6.1 (2.3)
Patient's global assessment of PsA (0-10), mean (SD)	4.0 (2.9)	2.9 (2.4)	6.2 (2.5)
HAQ (0-3), mean (SD)	1.2 (0.6)	1 (0.5)	1.5 (0.6)
MDA state, n (%)	121 (29.2)	108 (38.6)	14 (10.4)
VLDA state, n (%)	53 (12.8)	51 (18.2)	2 (1.5)

FIGURE A

Percentage of domains missed for patients in MDA state who self-reported LDA/REM (n=107) and who did not self-report LDA/REM (n=14).

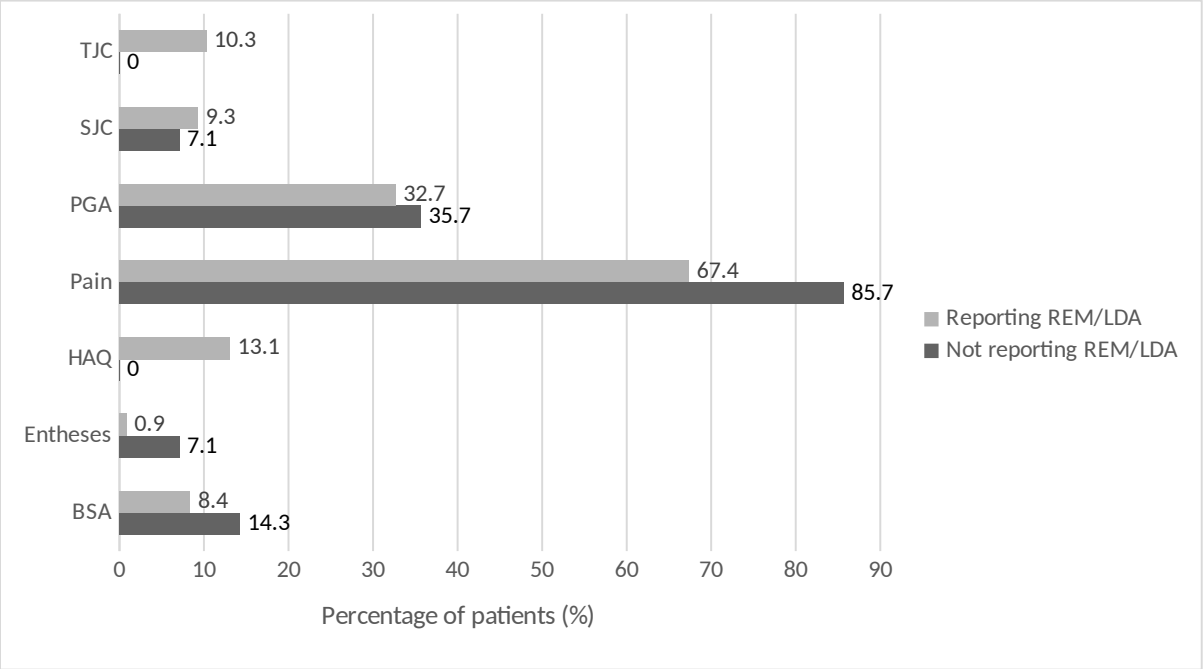

FIGURE B

Odds ratios of patients in MDA state not reporting REM/LDA for when each domain was missed.

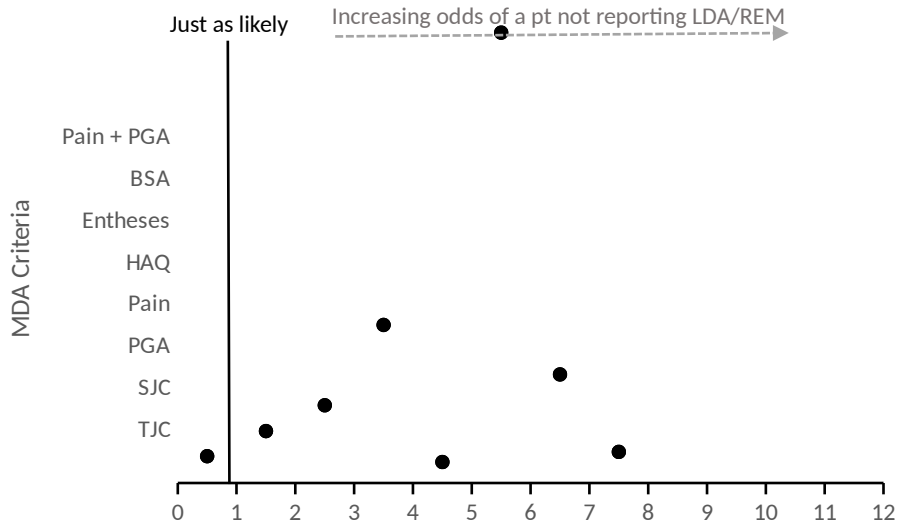

TABLE 3

Point-biserial correlation results between the number of MDA criteria met and patient-reported good status overall and for when each domain is not met.

	Correlation value	Significance
All patients	0.52	<0.001
Domain missed*		
TJC	0.46	<0.001
SJC	0.43	<0.001
PGA	0.45	<0.001
Pain	0.45	<0.001
HAQ	0.46	<0.001
Entheses	0.30	0.02
BSA	0.37	0.004
Pain and PGA	0.42	<0.001

TABLE 4

Chi square values for association between MDA status and patient-reported LDA/REM, specificity and PPV for when each domain is missed.

	Chi-square value (*p-value*)	MDA specificity	MDA PPV
MDA (total)		88.1	90.8
Domain missed*			
TJC	11.94 (<.001)	100	100
SJC	9.44 (.002)	98.5	90.9
PGA	23.00 (<.001)	95.8	87.5
Pain	32.76 (<.001)	90.8	85.7
HAQ	15.28 (<.001)	100	100
Entheses	0.30 (.584)	97.5	50.0
BSA	4.66 (.031)	92.6	81.8
Pain and PGA	18.56 (<.001)	95.8	85.3

Data Supplements

SUPPLEMENTAL FIGURE A.

Percentage of domains missed for patients who did not meet MDA state but self-reported LDA/REM (n=122).