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Performance of the 2017 EULAR/ACR criteria for idiopathic inflammatory myopathies in a cohort of patients from Latin America

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Abstract

We aimed to determine the performance of the 2017 European League Against Rheumatism/American College of Rheumatology (EULAR/ACR) classification criteria for idiopathic inflammatory myopathies (IIMs) in a cohort of Chilean patients. This single-center retrospective study included 151 patients with a clinical diagnosis of IIM. Patients were classified according to the 2017 EULAR/ACR classification criteria for IIM, and its performance was compared to the Bohan & Peter (B&P) classification criteria. A total of 135 patients (89.4%) met the EULAR/ACR criteria, and 140 (92.7%) patients met the B&P criteria. A total of 130 patients had IIM according to both the criteria; concordance rate was 29.2% for definite IIM, 6.2% for probable IIM, and 1.5% for possible IIM. The kappa coefficient of agreement was weak between the 2 classification criteria (κ = 0.39, SD 0.15–0.64). Against gold standard expert physician's diagnosis, sensitivity, and specificity of EULAR/ACR criteria was 0.86 and 0.85 to diagnose dermatomyositis, respectively, and 0.73 and 0.87 to diagnose polymyositis. The EULAR/ACR criteria showed good sensitivity and identified more patients with probable or definite IIM than the B&P criteria in a single-center cohort of patients with IIM in South America. The sensitivity of the EULAR/ACR criteria was slightly higher in patients with dermatomyositis, but lower in patients with polymyositis, than that of the B&P criteria.

Abbreviations: ADM = amyopathic dermatomyositis, B&P = Bohan &Peter, DM = dermatomyositis, EULAR/ACR = European League Against Rheumatism/American College of Rheumatology, IBM = inclusion body myositis, IIM = idiopathic inflammatory myopathies, IMCCP = International Myositis Classification Criteria Project, JDM = juvenile dermatomyositis, MSA = myositis-specific antibodies, PM = polymyositis.

Keywords: classification criteria, dermatomyositis, idiopathic Inflammatory myopathies, polymyositis

1. Introduction

Idiopathic inflammatory myopathies (IIM) are characterized by muscle inflammation and internal organ involvement. Based on their clinicopathological characteristics, the 4 main subgroups of IIM are dermatomyositis (DM), polymyositis (PM), immune-mediated necrotizing myopathy, and inclusion body myositis (IBM).[1]

Given their heterogeneous clinical presentation, it has been challenging to develop accurate tools to correctly diagnose and classify IIM and to evaluate activity, damage, and progression. The Bohan & Peter (B&P) criteria have been widely used as both diagnostic and classification criteria for IIM.[2] These criteria have been very useful, but are based on expert opinion and have some limitations, such as the absence of IBM and the potential to misclassify other muscle diseases as IIM.[3,4]

In 2017, the European League Against Rheumatism (EULAR) and the American College of Rheumatology (ACR)[5,6] developed and published new criteria for IIM and its major subgroups, which considered multiple variables, such as age at disease onset, proximal muscle weakness, skin manifestations, and laboratory tests, with or without muscle biopsy. Using these criteria, the degree of probability of the patient having the disease can be calculated by inputting the patient's information. Additionally, they allowed for subclassification into subgroups according to the age of onset and the presence of cutaneous manifestations.[6]

The EULAR/ACR criteria are based on data from children and adults of different ethnicities from Europe, America, and Asia; however, the original study only included one site from South America (Brazil), and few patients were of Hispanic ethnicity.[5,6] In this study, we sought to further determine the performance of the 2017 EULAR/ACR classification criteria for IIM in a cohort of Chilean patients in South America and to compare them to the more widely used B&P criteria.

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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2. Methods

2.1. Study design

We performed a single-center retrospective study of all patients with IIM evaluated at a tertiary referral medical center in Chile between 2014 and 2019. This study was approved by the Institutional Review Board of Pontificia Universidad Católica de Chile. We adhered to the guidelines set by the Declaration of Helsinki (modified 1989).

2.2. Study population

Patients evaluated at Pontificia Universidad Católica de Chile Medical Center were identified using the 10th revised International Classification of Diseases of M33 (DM/PM), M60.9 (myositis), or G72.4 (inflammatory myopathy) (177 patients). We then reviewed the electronic medical records of all the patients and included those with a clinical diagnosis of IIM as per expert physician. We considered the clinical diagnosis by the expert treating physician as the "gold standard" for the diagnosis of IIM.

2.3. Study measures

We collected demographic information, comorbidities, cutaneous and muscular symptoms, physical examination findings and biopsies, other findings such as arthritis, fever, Raynaud phenomenon, symptoms of gastroesophageal reflux, respiratory and cardiac involvement, presence of cancer (if present, type, and date of diagnosis), laboratory studies, autoantibodies, and treatments. This was assessed by chart review using progress notes, laboratory tests, imaging, and histology as available. We defined respiratory involvement as the presence of pulmonary fibrosis or ground glass opacities on high-resolution computed tomography of the chest or a forced vital capacity <70% on spirometry. Cardiac involvement was defined as left ventricular ejection fraction <45% not attributable to left heart disease with or without elevated cardiac enzymes or abnormal enhancement on cardiac magnetic resonance imaging. Antinuclear antibodies were identified by indirect immunofluorescence technique on HEp-2 substrate. Myositis-specific antibodies (MSA) were detected through routine clinical care using EUROLINE Autoimmune Inflammatory Myopathies 16 Ag (IgG), Euroimmun. All available muscle biopsies were evaluated by the same pathologist at Pontificia Universidad Católica de Chile using conventional histopathological examination and immunohistochemical staining (hematoxylin and eosin (H&E), modified Gomori trichrome stain, ATPase and nicotinamide adenine dinucleotide tetrazolium reductase). The study data were collected and managed using REDCap electronic data capture tools.[7]

2.4. Classification of patients

Patients were classified according to the 2017 EULAR/ACR classification criteria for IIM using a web-calculator (www.imm.ki.se/biostatistics/calculators/iim). All cases were categorized using the suggested cutoff points into 3 groups: definite (total score ≥ 7.5 without muscle biopsy and ≥8.7 with muscle biopsy), probable (≥5.5 without biopsy and ≥6.7 with biopsy), and possible IIM (≥5.3 without biopsy and ≥6.5 with biopsy), as recommended by the new EULAR/ACR criteria. Further subclassification into DM, amyopathic dermatomyositis (ADM), PM or immune-mediated necrotizing myopathy, IBM, juvenile DM (JDM), and juvenile myositis other than JDM was performed. The patients were also classified according to the B&P criteria.

2.5. Statistical analysis

Descriptive statistics were used to analyze the number of patients according to the physician's diagnosis, B&P, and EULAR/ACR criteria classification for IIM. The sensitivity of the EULAR/ACR scoring criteria against the gold standard expert physician's diagnosis was calculated and compared with those of the B&P criteria. Patients with definite, probable, and possible IIM were considered to meet EULAR/ACR and B&P criteria for the analysis of sensitivity. In addition, we also calculated the sensitivity of both sets of criteria considering only patients with definite IIM. The concordance rate was calculated as the number of subjects that were concordant over the total number of subjects assessed, using simple contingency tables. We calculated Cohen kappa coefficient of agreement (κ) to assess the performance of the 2017 EULAR/ACR classification criteria when compared to the B&P criteria. Statistical significance was defined as $P < .05$. All statistical analyses were performed using the SAS statistical software, version 9.3 (SAS Institute Inc., Cary, NC).

3. Results

3.1. Baseline characteristics

In total, 151 patients with IIM were included in this study (130 adults, 21 children). Our cohort was 78% female, 100% Hispanic/Latino, mean age at diagnosis was 43.3 ± 22.5 years, 102 (68%) patients presented with proximal muscle weakness, 93 (62%) with heliotrope rash, and 80 (53%) with Gottron papules. Ninty-one (60%) patients were positive for antinuclear antibodies, and 38 (25.2%) patients had at least 1 MSA. Fifty-eight (38.4%) patients underwent muscle biopsy, which was suggestive of IIM in 51 (33.8%) (Tables 1 and 2). The physician diagnoses are listed in Table 3.

3.2. Classification and subclassification of patients with IIM

A total of 135 patients (89.4%) met the EULAR/ACR criteria: 51 (34%) patients met the criteria for DM, 28 (19%) for PM, 1 (0.7%) for IBM, 33 (22%) for ADM, and 22 (15%) for JDM. A total of 140 (92.7%) patients met the B&P criteria: 34 (22.5%) were classified as PM and 106 (70.2%) as DM (Table 3).

Among the 135 patients who met the EULAR/ACR criteria, 106 (70.2%) patients were classified as having definite IIM, 27 (17.9%) as probable IIM, and 2 (1.3%) as possible IIM. Of 140 patients who met the B&P criteria, 42 (27.8%) were classified as definite, 57 (37.7%) as probable, and 41 (27.2%) as possible DM/PM (Table 4). A total of 130 (86.1%) patients had IIM according to both criteria; concordance rate was 29.2% for definite IIM, 6.2% for probable IIM, and 1.5% for possible IIM. The kappa coefficient of agreement was weak between the 2 classification criteria (κ = 0.39, SD 0.15–0.64).

Ten patients met the B&P criteria but did not meet the EULAR/ACR criteria, of whom 6 were classified as having possible PM, 2 as having possible DM, and 2 as having probable DM according to the B&P criteria. On the other hand, 5 patients met the EULAR/ACR criteria but did not meet the B&P criteria; all of them had DM (3 JDM and 2 ADM) according to the EULAR/ACR criteria. Six patients did not meet any set of criteria of whom 2 had a clinical diagnosis of DM, 2 JDM, 1 PM, and 1 nonspecific inflammatory myopathy.

3.3. Sensitivity and specificity of EULAR/ACR and B&P criteria

The sensitivity for detecting IIM was 0.88 for the EULAR/ACR criteria and 0.87 for B&P criteria. The sensitivity improved slightly when patients with only definite IIM were considered to meet criteria (0.91 for the EULAR/ACR criteria and 0.88 for the

Table 1

Demographic characteristics of the study cohort

	Patientsn (%)	Sample sizen
Female	117 (78)	151
Ethnicity		
Hispanic/Latino	151 (100)	151
Mean age (yrs ± SD)	43.3 ± 22.5	151
Mean disease duration (mo ± SD)	48.2 ± 46	151
Cutaneous involvement		
Heliotrope rash	93 (62)	118
Gottron papules	80 (53)	111
Gottron sign	64 (42.4)	94
Holster sign	44 (29.1)	63
Shawl sign	52 (34.4)	68
V-neck	74 (49.0)	87
Mechanic's hands	16 (10.6)	36
Periungual telangiectasia	58 (38.4)	75
Calcinosis	18 (11.9)	35
Scalp erythema	45 (29.8)	62
Pruritus	67 (44.4)	91
Alopecia	44 (29.1)	77
Muscle involvement		
Proximal muscle weakness	102 (68)	138
Dysphagia	36 (23.8)	81
Mean CK (U/L ± SD)	3360 (9360)	147
Mean LDH (U/L ± SD)	522.7 (437.1)	128
Mean AST (U/L ± SD)	147.1 (237.5)	140
Mean ALT (U/L ± SD)	121.6 (154.3)	137
Myopathy abnormalities on EMG	38 (25.2)	77
Muscle biopsy consistent with IIM	51 (33.8)	58
Interstitial lung disease	19 (12.6)	150
Malignancy (ever)	18 (11.9)	151
Autoantibodies		
Positive ANA	91 (60)	135
Jo-1	8 (5.3)	123
Mi2-alpha	5 (3.3)	38
Mi2-beta	6 (4.0)	38
Tif1	10 (6.6)	38
MDA5	1 (0.7)	38
Nxp2	3 (2.0)	38
Sae1	2 (1.3)	38
Ku	1 (0.7)	38
PM-Scl-100	1 (0.7)	38
PM-Scl-75	3 (2.0)	38
SRP	3 (2.0)	38
PL-7	2 (1.3)	38
PL-12	1 (0.7)	38
EJ	0	38
OJ	0	38
Ro52	14 (9.3)	122
Treatment (ever)		
Corticosteroids	143 (94.7)	151
Methotrexate	107 (70.9)	151
Mycophenolate mofetil	39 (25.8)	151
Azathioprine	48 (31.8)	151
Cyclophosphamide	7 (4.6)	151
Intravenous immunoglobulin	21 (13.9)	151
Rituximab	18 (11.9)	151

ANA = antinuclear antibodies, ALT = alanine aminotransferase, AST = aspartate aminotransferase, CK = creatine kinase, EMG = electromyography, IIM = idiopathic inflammatory myopathy, LDH = lactate dehydrogenase, SD = standard deviation.

B&P criteria). Sensitivity and specificity of EULAR/ACR criteria to diagnose DM was 0.86 and 0.85, respectively. The sensitivity of the EULAR/ACR criteria for PM diagnosis was 0.73, and the specificity was 0.87. Sensitivity and specificity of B&P criteria to diagnose DM was 0.85 and 0.82 and for PM was 0.93 and 0.77, respectively. In the subset of patients who underwent muscle biopsy (51 patients), the sensitivity and specificity of the

Table 2

Features of the ACR/EULAR classification criteria for adult and juvenile idiopathic inflammatory myopathies in the study cohort

	Patientsn (%)	Sample sizen
1. Was a muscle biopsy performed?	51 (33.8)	58
Classification criteria		
2. Age of onset of first symptom assumed to be related to the disease ≥18 years and <40 years	41 (27.2)	151
3. Age of onset of first symptom assumed to be related to the disease ≥40 years	90 (59.6)	151
Muscle weakness		
4. Objective symmetric weakness, usually progressive, of the proximal upper extremities	77 (51.3)	132
5. Objective symmetric weakness, usually progressive, of the proximal lower extremities	91 (60.7)	133
6. Neck flexors are relatively weaker than neck extensors	43 (28.7)	87
7. In the legs proximal muscles are relatively weaker than distal muscles	94 (62.7)	133
Skin manifestations		
8. Heliotrope rash	93 (61.6)	118
9. Gottron papules	80 (53)	111
10. Gottron sign	64 (42.4)	94
Other clinical manifestations		
11. Dysphagia or esophageal dysmotility	36 (24)	81
Laboratory measurements		
12. Anti-Jo-1 (anti-histidyl-tRNA synthetase) autoantibody present	8 (5.3)	123
13. Elevated serum levels of creatine kinase (CK)* ***or*** lactate dehydrogenase (LDH)* ***or*** aspartate aminotransferase (ASAT/AST/SGOT)* ***or*** alanine aminotransferase (ALAT/ALT/SGPT)*	136 (90.1)	151
Muscle biopsy features- presence of:		
14. Endomysial infiltration of mononuclear cells surrounding, but not invading, myofibres	10 (22.2)	58
15. Perimysial and/or perivascular infiltration of mononuclear cells	20 (44.4)	58
16. Perifascicular atrophy	40 (87)	58
17. Rimmed vacuoles	1 (2.2)	58

EULAR/ACR = European League Against Rheumatism/American College of Rheumatology.

Table 3

Number of patients according to physician's diagnosis and classified according to the Bohan and Peter (B&P) and the EULAR/ACR criteria.

	Clinical diagnosis	EULAR/ACR	B&P
Dermatomyositis	84 (55.6)	51	106
Polymyositis	15 (9.9)	28	34
Amyopathic Dermatomyositis	12 (7.9)	33	–
Juvenile dermatomyositis	21 (13.9)	22	–
Nonspecific inflammatory myopathy	10 (6.6)	–	–
Necrotizing myopathy	9 (6.0)	–	–
Inclusion body myositis	0	1	–
Total	151	135	140

EULAR/ACR = European League Against Rheumatism/American College of Rheumatology.

Table 4

Classification of IIM patients based on both criteria sets.

	EULAR/ACR	B&P
Definite	106 (70.2)	42 (27.8)
Probable	27 (10.6)	57 (37.7)
Possible	2 (1.3)	41 (27.2)
Non-IIM	16 (10.6)	11 (7.3)

B&P = Bohan & Peter, EULAR/ACR = European League Against Rheumatism/American College of Rheumatology, IIM = idiopathic inflammatory myopathy.

Table 5

Performance of B&P and EULAR/ACR criteria against physician diagnosis.

		Overall cohort		Subgroup with biopsy	
	Subclassification	Sensitivity	Specificity	Sensitivity	Specificity
B&P	DM	0.85	0.82	0.86	0.9
	PM	0.93	0.77	0.9	0.65
EULAR/ACR	DM	0.86	0.85	0.7	0.9
	PM	0.73	0.87	0.9	0.63

B&P = Bohan &Peter, DM = dermatomyositis, EULAR/ACR = European League Against Rheumatism/American College of Rheumatology, PM = polymyositis.

EULAR/ACR criteria were 0.7 and 0.9 for DM and 0.9 and 0.63 for PM (Table 5).

4. Discussion

This study demonstrated the applicability of the EULAR/ACR criteria in a single-center cohort of IIM patients in South America. In our cohort, approximately 90% of the patients were classified as having IIM according to the new criteria. The major subgroups recognized by these criteria were developed through an international multidisciplinary collaboration, the International Myositis Classification Criteria Project (IMCCP).[6] The Hispanic group was underrepresented in the IMCCP, accounting for only 5.2% of the cohort. Our findings support the use of the new criteria in this population and demonstrate their usefulness in patients from different ethnic backgrounds.

Although the B&P criteria were able to identify more patients (92%) in our cohort, we showed that the number of patients classified as probable or definite IIM was higher when using the EULAR/ACR than when using the B&P criteria. This is particularly important for research purposes, where a high specificity is required and patients with a higher probability of disease should be included.

We found that the level of concordance between the EULAR/ACR and B&P criteria, especially for classifying possible and probable diseases, was low. Similarly, a single-center study of 439 patients with IIM from Sweden reported low concordance ($\kappa = 0.253$, $P < .001$) between both sets of criteria.[8] This observation was also reported by Pinto et al,[3] who studied 111 patients with IIM from a tertiary center in India and showed that the agreement between the 2 classification criteria was weak ($\kappa = -0.331$). However, this was not the case in the original validation cohort, where the comparison between the EULAR/ACR and B&P criteria showed 89% agreement ($\kappa = 0.71$, $P < .00001$).[6] This might be partially explained because patients with insufficient available information in the IMCCP cohort were not included.

Several studies performed in Asian and Caucasian populations have shown greater sensitivity of the EULAR/ACR criteria when compared to the B&P criteria to diagnose IIM.[9,10] In our study, we confirmed that the EULAR/ACR criteria had a higher sensitivity than the B&P criteria, especially when considering patients who meet criteria for definite IIM. Regarding subclassification, the sensitivity and specificity of the EULAR/ACR criteria in patients with DM were slightly higher than those of the B&P criteria. However, the sensitivity of the EULAR/ACR criteria was lower in patients with PM, indicating a lower likelihood of detecting PM. This lower sensitivity might be at least partially explained by the omission of autoantibodies other than anti-Jo-1 from the new set of criteria. It is possible that adding MSA would improve the criteria performance, as recently suggested by a study of 524 MSA-positive myositis patients from the Johns Hopkins Myositis Center, where 91% of the patients were correctly classified using the EULAR/ACR classification criteria; however a significant number of patients with autoantibodies against HMGCR, SRP, and PL7, were misclassified as "not-myositis." Authors also showed that MSA better predicted clinical phenotypes than the EULAR/ACR-defined subgroups.[11] This should be carefully evaluated in future studies as these autoantibodies become more widely available.[12] Also, the existence of PM remains debatable. In a recent study of 37 patients from a UK tertiary myositis clinic classified as PM according to both sets of criteria, only 9 (24.3%) remained classified as PM after thorough review and physician's consensus decisions.[13] The authors suggested that the EULAR/ACR criteria consider a wide range of PM. In our study, the sensitivity for diagnosing PM improved and specificity decreased in the subgroup of patients with available muscle biopsy data. However, in Chile, muscle biopsy is generally performed only when differential diagnosis is difficult; thus, only a small number of included patients had muscle pathology.

One limitation of our study is its single-center design and the lack of a control group, which precludes us from calculating the specificity of the new set of criteria. In addition, the fact that few patients underwent muscle biopsies or MSA did not allow us to reliably evaluate the performance of the new criteria in these subgroups of patients. However, the major strength of this study is that it is the first attempt to validate new criteria in Latin America. Additionally, this study involved a clinically well-characterized cohort of patients with IIM followed at tertiary center.

In conclusion, the EULAR/ACR performed well in a cohort of Latin American patients. Because classification criteria are essential for the inclusion of comparable patients in clinical studies, ethnic or geographical differences should be considered.

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