

Developing Classification Criteria for Polymyalgia Rheumatica: Comparison of Views from an Expert Panel and Wider Survey

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ABSTRACT. *Objective.* This report summarizes the findings from a consensus process to identify potential classification criteria for polymyalgia rheumatica (PMR).

Methods. A 3-stage hybrid consensus approach was used to develop potential PMR classification criteria. The first stage consisted of a facilitated meeting of 27 international experts who anonymously rated the importance of 68 potential criteria. The second stage involved a meeting of the experts, who were provided with the results of the first round of ratings and were then asked to re-rate the criteria. In the third stage, the wider acceptance of the 43 criteria that received > 50% support at round 2 was evaluated using an extended mailed survey of 111 rheumatologists and 53 nonrheumatologists in the United States, Canada, and Northern and Western Europe.

Results. A total of 68 and 50 criteria were identified and rated in round 1 and round 2, respectively. In round 2, 43 of the 50 items achieved at least 50% support, including 10 core criteria achieving 100% support. In round 3, over 70% of survey respondents agreed on the importance of 7 core criteria. These were age \geq 50 years, duration \geq 2 weeks, bilateral shoulder and/or pelvic girdle aching, duration of morning stiffness > 45 min, elevated erythrocyte sedimentation rate, elevated C-reactive protein, and rapid steroid response (> 75% global response within 1 wk to prednisolone/prednisone 15–20 mg daily). Among physical signs, more than 70% of survey respondents agreed on the importance of assessing pain and limitation of shoulder (84%) and/or hip (76%) on motion, but agreement was low for peripheral signs like carpal tunnel, tenosynovitis, and peripheral arthritis.

Conclusion. There are differences in opinion as to what PMR is and how it should be treated. These findings make it important to develop classification criteria for PMR. The next step is to perform an international prospective study to evaluate the utility of candidate classification criteria for PMR in patients presenting with the polymyalgic syndrome. (First Release Nov 15 2007; J Rheumatol 2008;35:270–7)

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Polymyalgia rheumatica (PMR) is a common disease in the elderly. It is conventionally treated with longterm oral steroids and is one of the most common indications for longterm steroid use in the community¹. The treatment can be prolonged and numerous steroid side effects have been reported². In the United Kingdom, age-adjusted incidence of diagnosed PMR was reported to have increased by 35% between 1990 and 2001 (from 6.9 to 9.3 per 10,000 person-years)³. It is not clear whether this indicates a true increase, increased recognition, or overdiagnosis of PMR.

There is considerable uncertainty related to diagnosis and outcomes in patients presenting with the polymyalgic syndrome (proximal pain and stiffness)⁴ and differences in the sensitivity of the various sets of diagnostic criteria in use⁵ (Table 1). International researchers have, over the years, debated the issues of guidelines for the diagnosis, management, and disease response measures in PMR. A recent prospective study has highlighted the heterogeneity of its

Table 1. Summary of current diagnostic criteria for polymyalgia rheumatica.

Criteria	Hunder ²⁶	Healey ²⁷	Bird ²⁹	Jones ²⁸
1 Age ≥ 50 years	+	+	≥ 65 years	+
2 Bilateral aching of neck, shoulders, pelvic girdle	+ Any 2	+ Any	+ Shoulder pain and stiffness	+ Shoulder and pelvic girdle pain without weakness
3 Morning stiffness > 1 h	+	+	+	+
4 Duration of symptoms	≥ 1 mo	≥ 1 mo	< 2 wks	≥ 2 mo unless treated
5 ESR > 40 mm/h	+	+	+	ESR > 30; CRP > 6 mg/l
6 Depression and/or loss of weight	–	–	+	–
7 Exclusion of other diagnosis	+	+	–	+
8 Rapid response to prednisolone (≤ 20 mg/day)	–	+	–	+
9 Others	–	–	Bilateral upper arm tenderness; depression and/or loss of weight	–
Diagnosis	All criteria need to be fulfilled	All criteria need to be fulfilled	Any 3 or one plus positive temporal artery biopsy	All criteria need to be fulfilled

* Onset of symptoms.

course, major influence on quality of life, uncertainty related to its diagnosis, and high incidence of adverse events⁶. These findings along with wide variations in practice in the management of this common disease suggest the need for guidelines for safe diagnosis, ongoing monitoring of disease, vigilance regarding an alternative diagnosis, and early referral of patients with atypical features and poor steroid response. This uncertainty and heterogeneity make it important to develop validated classification criteria for patients presenting with the polymyalgic syndrome. Classification criteria for PMR will facilitate differentiation of this clinical syndrome as a distinct disease entity (separate from conditions such as seronegative and seropositive inflammatory arthritis and manifold other conditions sharing similar clinical characteristics), and also, prediction of disease- and treatment-related outcomes.

Research evidence on the diagnosis and the effectiveness of different interventions for the treatment of PMR is limited. Studies conducted in primary care are rare. The few randomized controlled trials⁷⁻¹² that have been conducted in secondary care settings have been based on small samples and have had little effect on the conventional treatment of PMR with oral steroids.

The diagnosis of PMR presents many difficulties and different criteria have been used in studies of PMR¹³. Studies have also demonstrated alterations of PMR diagnoses with longterm followup^{14,15}. It was noted that many patients with an initial PMR diagnosis were subsequently found to have conditions such as rheumatoid arthritis (RA), systemic lupus erythematosus, and spondyloarthropathies.

Despite oral steroids remaining the standard treatment for PMR, there is no evidence from randomized trials for the effectiveness of alternative initial doses or dose tapers. Observational studies have shown differences in steroid requirements in individual patients^{16,17}, that low maintenance doses were related to low initial doses¹⁸, and that higher initial doses and rapid steroid tapering were associated with a

higher frequency of relapses¹⁹. However, these observational studies may be confounded by more severely ill patients receiving higher initial doses.

Most observational studies recommend that steroid doses are reduced gradually to prevent relapse of symptoms, with studies reporting around half of patients having relapses and median duration of steroid treatment around 2–3 years²⁰. Another study proposed 3 categories of disease course: a short duration of treatment following a rapid response to steroids and without significant relapse; a rapid response to steroids requiring extended treatment to control disease flares; and an incomplete resolution of symptoms requiring increased doses of steroids and extended treatment to control disease flares²¹. The benefits from treatment with steroids need to be balanced with the increased risk of adverse outcomes such as diabetes and fractures².

These uncertainties in the diagnosis and management of PMR led to a recognition for the development of classification criteria. We present the findings from a 3-stage consensus process, involving experts and a wider community of rheumatologists and nonrheumatologists, to identify potential PMR classification criteria.

MATERIALS AND METHODS

The potential classification criteria were developed using a 3-stage hybrid consensus approach, drawing both on the benefits of convened meetings of experts and on a wider consultation using Delphi-type mailed surveys^{22,23} (Figure 1).

The first stage consisted of a facilitated, convened meeting of an international panel of experts at The Third International Conference on PMR and Giant Cell Arteritis in July 2005. In the absence of any agreed definition for an “expert”²⁴, 2 authors (BD, ELM) and the conference organizing committee invited a purposive, nonexhaustive sample of individuals attending the conference to take part in the panel. The selection process aimed to create a panel comprising an international group of rheumatologists with an interest in PMR (as demonstrated by significant involvement in PMR research) as well as other rheumatologists, primary care physicians, methodologists, and statisticians. Invited panelists were also asked to suggest additional names for invi-

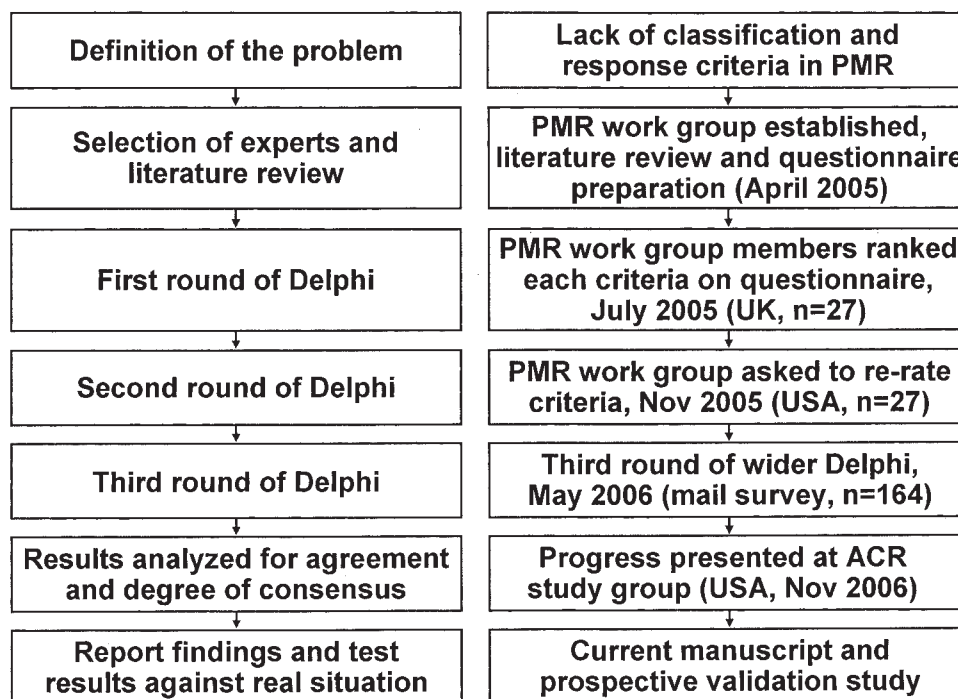


Figure 1. PMR classification criteria development project²⁴.

tation. All panelists were provided with a comprehensive literature review of studies of the diagnosis (including imaging methods such as ultrasonography) and treatment of PMR. The meeting was facilitated in order to identify a broad list of potential criteria that may be of use in the classification of PMR. Following the meeting, a questionnaire was developed and distributed so that panel members could anonymously rate the usefulness of the potential criteria. For example, panelists were asked to rate morning stiffness as a criterion for classification. For each item the degree of consensus was categorized as > 90%, > 80%, or > 50% support.

The second stage of the process involved another convened meeting of the panel of experts at the American College of Rheumatology (ACR) Annual Scientific Meeting in November 2005. At this meeting, panelists were provided with the results of the first round of ratings. All potential criteria and their ratings were evaluated during the facilitated meeting and panelists were then asked to re-rate items.

In the third stage, the wider acceptance of the items given > 50% support by the expert panel at round 2 was evaluated using a mailed survey of other rheumatologists and nonrheumatologists. Rheumatologists were randomly selected from membership lists of the ACR (including non-American members) and the British Society for Rheumatology. Nonrheumatologists were recruited by random selection from a list of primary care practitioners and ophthalmologists in Essex, England, and family practitioners and general internists in Minnesota, Wisconsin, and Iowa randomly selected from state physician directories. Items were regarded as achieving "perfect consensus" or "consensus" when 95% and 80%, respectively, of respondents supported the importance of a criterion.

In addition, a brief survey was conducted at the same time and this was the first expert panel on imaging techniques in the investigation of PMR. A questionnaire was sent to 25 rheumatologists from the PMR Work Group to assess their views on the importance (essential, less important, or not important) and availability (routinely available, not always available, or unavailable) of magnetic resonance imaging (MRI), skeletal ultrasound, and 18F-fluorodeoxyglucose positron emission tomography (FDGPET) for the evaluation of patients with PMR.

Statistical methods. Descriptive statistics were used to summarize the survey

responses. For each item, the rate of agreement was estimated as the number of affirmative responses over the total number of responses. Missing values were treated as nonresponses and were excluded from calculations of agreement rates. Items that received > 95% agreement were considered as consensus items. Chi-square tests were used to compare the rate of agreement between work group members and rheumatologist and nonrheumatologist respondents.

RESULTS

There were 27 participants in the expert panel for round 1, the majority being research-active rheumatologists and internists (Appendix). During the facilitated discussion, the expert panel agreed on 4 key features that should underpin the process for developing PMR classification criteria. First, the purpose of developing PMR classification criteria was to distinguish PMR from other conditions with a polymyalgic presentation (pain and stiffness). Second, there was agreement that PMR diagnosis is a stepped process, starting with the inclusion or exclusion of patients presenting with the polymyalgic syndrome based on clinical features, findings on examination, and laboratory investigations. Third, there was a recognition of the importance of the initial response to steroid therapy in establishing a PMR diagnosis. Finally, the panel agreed that any candidate criteria would need to be evaluated in a prospective study because of the lack of existing research evidence (Table 2). These principles and further discussion guided the development of the questionnaire to identify and assess the level of support for specific potential criteria for classifying PMR.

In round 1, a total of 68 potential criteria were identified and rated by members of the expert panel and 50 reached

Table 2. PMR Work Group consensus items from first Delphi exercise.

- 1. The purpose of developing PMR classification criteria is to distinguish PMR from other conditions with a polymyalgic presentation**
- 2. The diagnosis in PMR is a stepped process**

Patients presenting with polymyalgic syndrome should be evaluated on the basis of inclusion and exclusion criteria. These criteria would be based on clinical features, findings on examination, and laboratory investigations
- 3. The need to standardize initial response to steroid therapy in PMR**

Several existing diagnostic criteria incorporate the steroid response as a criterion and many clinicians attribute it a pivotal role for the diagnosis of PMR. Yet no valid scientific evidence is available as to what that might be. The work group agreed (> 75% agreement) that this might be > 75% global response (clinical and laboratory measures) within 7 days to steroid challenge with oral 15 mg prednisone or prednisolone and subsequent resolution of inflammatory indices
- 4. The need for a prospective study to evaluate the disease course from presentation in patients included on the basis of the mandatory “core” criteria of proximal pain and stiffness**

The group agreed that the candidate criteria need to be validated in a prospective study and endorsed a detailed process of evaluation based on symptoms, examination findings, and investigations. A prospective study will also have the additional strength of a standardized steroid treatment and standardized evaluation at prespecified intervals over a 12-month period

PMR: polymyalgia rheumatica.

> 50% consensus. Criteria that received little consensus because of limited availability were cytokine measurements (i.e., interleukin 1, IL-2, IL-6) and PET scanning.

In round 2, the 27 participants in the expert panel met again for a facilitated discussion of the 50 criteria items from round 1 with > 50% support. After privately re-rating the items there were 43 items that achieved at least 50% support, including 10 achieving 100% support (Table 3).

In round 3, the extended survey, a questionnaire comprising these 43 potential classification criteria, was mailed to 190 rheumatologists and 85 nonrheumatologists. Responses were received from 111 (58.4%) rheumatologists, 49 from the United States and 62 from 15 European countries and Canada. Responses were received from 53 (62.4%) nonrheumatologists, 29 from the US and 24 from the UK.

Seven of the 10 items that had 100% support from the expert panel received at least 70% support from survey respondents (Table 3). The 3 items with little support were abrupt onset in < 1 week (25%), systemic signs/symptoms (38%), and neck aching (35%). Among physical signs, > 70% of respondents agreed with the experts on the importance of assessing pain and limitation of shoulder (84%) and/or hip (76%) on motion, but agreement was low for peripheral signs like carpal tunnel syndrome, tenosynovitis, and peripheral arthritis. In both groups, $\geq 75\%$ agreed that a diagnosis of RA, lupus, vasculitis, inflammatory myopathy, septic arthritis, active neoplasia (active infection and cancer were core exclusions), active thyroid disease, and drug-related myalgia would exclude the PMR diagnosis in a classification criteria study of the polymyalgic syndrome.

There were some notable differences in perception of PMR between rheumatologists and nonrheumatologists. Of the 10 core items, there was little difference between the responses of rheumatologists and nonrheumatologists (Table 4). However,

agreement was low on the value of morning stiffness, where 77% of rheumatologists and only 57% of nonrheumatologists considered it as an important criterion ($p = 0.016$). Nearly 100% of both groups agreed on the importance of rapid and complete response to low-dose steroids. Nonrheumatologists placed less importance on the value of anti-cyclic citrullinated peptide antibodies (40% vs 24%; $p = 0.09$). Among examination characteristics, nonrheumatologists placed less importance on distal extremity swelling (33% vs 17%; $p = 0.04$), tenosynovitis (36% vs 7%; $p < 0.001$), and peripheral arthritis (45% vs 17%; $p = 0.001$), and more importance on shoulder tenderness (58% vs 90%; $p < 0.001$) and hip tenderness (50% vs 82%; $p < 0.001$). Among exclusion diagnoses, rheumatologists and nonrheumatologists disagreed to some extent on the importance of excluding active thyroid diseases (80% vs 61%; $p = 0.015$) and Parkinson's disease (52% vs 36%; $p = 0.08$). Eighty percent or more of both groups agreed on the importance of excluding diagnoses of RA, lupus, vasculitis, inflammatory myopathy, septic arthritis, active neoplasia, and drug-related myalgia.

Results from the survey of imaging indicated that there was limited availability of MRI or FDGPET scans for the routine investigation of PMR, as reported by 86% and 70% of rheumatologists, respectively, and only 14% felt shoulder MRI was essential in evaluating PMR. In contrast, 65% of rheumatologists reported that musculoskeletal ultrasonography was routinely available.

DISCUSSION

Our study has identified widespread support for some proposed classification criteria whereas others were considered to have little potential. Differences in the views of the expert panel and participants in the wider survey, and also between rheumatologists and nonrheumatologists, provide some

Table 3. Results of the work group experts and survey respondents (10 core items are shown in bold type).

Variable	2nd Consensus Ratings by Experts (n = 27), n (%)	3rd Survey Respondents (n = 164), n (%)
Core Criteria		
Age ≥ 50 yrs	Consensus	139 (86)
Onset abrupt < 1 wk	Consensus	37 (25)
Duration ≥ 2 wks	Consensus	125 (81)
Systemic sign/symptoms	Consensus	57 (38)
Bilateral shoulder and/or pelvic girdle ache	Consensus	157 (98)
Neck aching	Consensus	51 (35)
Morning stiffness duration > 45 min	Consensus	109 (71)
Erythrocyte sedimentation rate	Consensus	141 (90)
C-reactive protein	Consensus	108 (71)
Laboratory tests		
Thyroid-stimulating hormone	21 (78)	119 (77)
Alkaline phosphatase	16 (59)	81 (53)
Creatinine kinase	21 (78)	122 (79)
Complete blood count	23 (85)	150 (95)
Serum protein electrophoresis	16 (59)	84 (56)
Rheumatoid factor	25 (93)	103 (66)
Anti-CCP antibody	19 (70)	50 (36)
Physical examination		
Shoulder tenderness	25 (93)	106 (68)
Shoulder pain on motion	27 (100)	133 (84)
Shoulder limitation	23 (85)	82 (53)
Hip tenderness	24 (89)	91 (60)
Hip pain on motion	26 (96)	120 (76)
Hip limitation	23 (85)	61 (43)
Neck	26 (96)	67 (45)
Carpal tunnel	19 (70)	16 (11)
Distal extremity swelling	21 (78)	42 (28)
Tenosynovitis	22 (81)	40 (27)
Peripheral arthritis	17 (63)	54 (36)
Response to therapy		
Steroid response	Consensus	157 (99)
Prednisone dose (mg/day)		
10	4 (15)	21 (13)
15	14 (52)	59 (37)
20	6 (22)	65 (41)
25	3 (11)	5 (3)
> 25		9 (6)
Rapid response		
1–3 days	14 (52)	91 (58)
4–7 days	12 (44)	67 (42)
Improvement		
> 50–74%	6 (22)	39 (24)
75–90%	13 (48)	90 (56)
> 90%	7 (26)	31 (19)
Exclusion diagnoses		
Rheumatoid arthritis/other inflammatory	27 (100)	150 (95)
Systemic lupus erythematosus	27 (100)	134 (86)
Vasculitis	27 (100)	124 (82)
Inflammatory myopathy	27 (100)	146 (95)
Osteoarthritis of hip	3 (11)	47 (31)
Osteoarthritis of shoulder	4 (15)	53 (34)
Septic arthritis or other infectious disease	27 (100)	124 (81)
Adhesive capsulitis	15 (56)	67 (44)
Active neoplasia	26 (96)	135 (86)
Fibromyalgia or other chronic pain syndrome	18 (67)	86 (57)
Active thyroid disease	19 (70)	111 (74)
Metabolic bone diseases	16 (59)	84 (58)
Parkinson's disease	18 (67)	69 (47)
Drug related myalgia/arthralgias	24 (89)	130 (86)

CCP: cyclic citrullinated peptide.

Table 4. Differences between rheumatologists and nonrheumatologists, third Delphi survey respondents.

Variable	Rheumatologists (n = 111), n (%)	Non-rheumatologists (n = 53), n (%)	p
Core criteria			
Age ≥ 50	98 (89)	41 (80)	0.13
Onset abrupt < 1 wk	25 (24)	12 (27)	0.76
Duration ≥ 2 wks	83 (80)	42 (84)	0.53
Systemic sign/symptoms	38 (37)	19 (40)	0.65
Bilateral shoulder and/or pelvic girdle ache	108 (98)	49 (96)	0.43
Neck aching	36 (36)	15 (34)	0.86
Morning stiffness duration > 45 min	82 (77)	27 (57)	0.016
Erythrocyte sedimentation rate	95 (89)	46 (92)	0.54
C-reactive protein	73 (68)	35 (76)	0.33
Laboratory tests			
Thyroid-stimulating hormone	78 (74)	41 (82)	0.29
Alkaline phosphatase	54 (51)	27 (57)	0.49
Creatinine kinase	83 (78)	39 (83)	0.45
Complete blood count	100 (93)	50 (98)	0.22
Serum protein electrophoresis	64 (62)	20 (44)	0.05
Rheumatoid factor	68 (64)	35 (71)	0.37
Anti-CCP antibody	42 (40)	8 (24)	0.09
Physical examination			
Shoulder tenderness	61 (58)	45 (90)	< 0.001
Shoulder pain on motion	93 (86)	40 (80)	0.33
Shoulder limitation	56 (53)	26 (51)	0.78
Hip tenderness	51 (50)	40 (82)	< 0.001
Hip pain on motion	85 (79)	35 (70)	0.19
Hip limitation	41 (42)	20 (43)	0.89
Neck	44 (43)	23 (50)	0.41
Carpal tunnel	13 (13)	3 (7)	0.28
Distal extremity swelling	34 (33)	8 (17)	0.040
Tenosynovitis	37 (36)	3 (7)	< 0.001
Peripheral arthritis	46 (45)	8 (17)	0.001
Response to therapy			
Steroid response	106 (98)	51 (100)	0.33
Prednisone dose (mg/day)			0.13
10	16 (15)	5 (10)	
15	43 (40)	16 (31)	
20	41 (38)	24 (46)	
25	4 (4)	1 (2)	
> 25	3 (3)	6 (12)	
Rapid response			0.045
1–3 days	68 (63)	23 (46)	
4–7 days	40 (37)	27 (54)	
Improvement			0.91
> 50–74%	27 (25)	12 (23)	
75–90%	61 (56)	29 (56)	
> 90%	20 (19)	11 (21)	
Exclusion diagnoses			
Rheumatoid arthritis/other inflammatory	101 (94)	49 (98)	0.23
Systemic lupus erythematosus	90 (86)	44 (88)	0.70
Vasculitis	85 (82)	39 (83)	0.85
Inflammatory myopathy	102 (95)	44 (96)	0.93
Osteoarthritis of hip	31 (30)	16 (33)	0.64
Osteoarthritis of shoulder	34 (32)	19 (40)	0.36
Septic arthritis or other infectious disease	85 (81)	39 (80)	0.84
Adhesive capsulitis	48 (45)	19 (41)	0.65
Active neoplasia	92 (84)	43 (90)	0.39
Fibromyalgia or other chronic pain syndrome	57 (54)	29 (62)	0.39
Active thyroid disease	83 (80)	28 (61)	0.015
Metabolic bone disease	53 (53)	31 (69)	0.07
Parkinson's disease	53 (52)	16 (36)	0.08
Drug related myalgia/artralgias	92 (87)	38 (84)	0.70

insight into variation in the diagnosis and treatment of PMR in practice.

Classification criteria are not synonymous with diagnostic criteria²⁵, although in practice classification criteria are sometimes used for diagnosis and several sets of PMR “diagnostic” criteria are based on study eligibility criteria²⁶⁻²⁸. Given this overlap it is still useful to compare the results from our study with the criteria in Table 1. The larger number of criteria from this study is expected, given that these are potential criteria that will be evaluated in a prospective study. Perhaps the most surprising difference is the diminishing support for morning stiffness as a criterion from rheumatologists and nonrheumatologists in the survey despite its inclusion in all existing diagnostic criteria. This raises a fundamental question as to what PMR is and whether it exists in the absence of stiffness, something that will hopefully be resolved with the development of classification criteria. It also raises the problem of whether it is possible for patients and clinicians to reliably distinguish pain and stiffness, and additional challenges of defining these concepts in studies with international recruitment. Our results may also indicate the possibility of overdiagnosis rather than underdiagnosis of PMR, particularly by nonrheumatologists.

The abrupt onset of symptoms, which received full support from the expert panel, is featured only in the Bird criteria²⁹. The difference between the expert panel and survey results may be a semantic difference because rheumatologists and nonrheumatologists in the survey may prefer a less strict definition of abrupt (perhaps < 2 weeks). Allowing a chronic onset of PMR has the inherent danger of misclassifying chronic mimicking illnesses including local degenerative conditions as PMR.

The lack of wider recognition of peripheral involvement in PMR suggests that differences between several diagnoses related to arthritis in the elderly, i.e., PMR, seronegative RA, remitting seronegative symmetrical synovitis with pitting edema (RS3PE), etc., may only be differences of terminology and perception. Only a prospective study will demonstrate whether there are indeed true differences of outcome. Lack of agreement on neck involvement is intuitively easier to understand since neck pain on its own (without other PMR features) would suggest other diagnoses.

There was a trend towards nonrheumatologists using higher doses that favors a misinterpretation of the ubiquitous non-specific response to steroids in any inflammatory illness. Other primary care studies also suggest that general practitioners tend to use higher doses for the treatment of PMR (K. Barraclough, personal communication).

The main strengths of our study are the use of a transparent process to elicit opinions, and the ability of the expert panel to revise those opinions following discussion. The relatively large size of the expert panel allowed the participation of a range of acknowledged experts on PMR from many countries, but may have limited their involvement in more detailed discussion. The nonrheumatologists surveyed were limited to

those based in the US and UK because the questionnaire was in English. It is possible that differences between the expert panel and the survey occurred because respondents to the survey were not exposed to the arguments put forward at the convened meeting. It has been recommended that the reasons for controversial decisions by convened groups should be provided to participants in later wider surveys, although this was not done in our study.

Our study suggests that, in the absence of a gold-standard diagnostic test, there are differences in opinion as to what PMR is as well as how it should be treated. These findings make it important to develop classification criteria for PMR. The next stage will be to perform an international prospective study to validate these candidate classification criteria for PMR in patients presenting with the polymyalgic syndrome.

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APPENDIX

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