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*Ann Rheum Dis* published online 13 May 2008;  
doi:10.1136/ard.2008.088526

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## Validity of the Polymyalgia Rheumatica Activity Score in Primary Care Practice

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### Grant support:

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**Word count** (body of text): 2642

### Contribution of each author to the paper:

**Study design.** Binard, De Bandt, Saraux.

**Acquisition of data.** Lefebvre, Binard, De Bandt, Berthelot, Saraux.

**Analysis and interpretation of data.** Binard, Lefebvre, Saraux.

**Manuscript preparation.** Binard, Lefebvre De Bandt, Berthelot, Saraux.

**Statistical analysis.** Binard, Lefebvre, Saraux.

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**Abstract**

**Objective:** To evaluate the validity and reliability of the polymyalgia rheumatica (PMR) activity score (PMR-AS) for relapse diagnosis by GPs, who manage a large proportion of patients with PMR.

**Methods:** We used seven clinical vignettes of PMR, for which 35 rheumatologists previously made a diagnosis of relapse or no relapse with greater than 80% agreement. These vignettes were submitted to 163 general practitioners (GPs), who were asked to assess disease activity using a visual analog scale (VASph), this being the only physician-dependent component of the PMR-AS. We used the 1116 available vignette-GP combinations to assess differences in VASph assessed by GPs versus rheumatologists. We evaluated statistical associations linking a relapse diagnosis by the rheumatologists (the reference standard) to the value of the GP-assessed PMR-AS or its components (GP-assessed VASph, VAS pain score, C-reactive protein, morning stiffness, and elevation of upper limbs).

**Results:** We found no significant differences between VASph scores by GPs versus rheumatologists for any of the vignettes. A relapse diagnosis was strongly associated with  $\text{PMR-AS} \geq 7$  (sensitivity, 99.4%; specificity, 93.3%; agreement, 95.9% [95CI, 94.5-97.0%] with  $\kappa=0.92$ ). Of the 590 GP-vignette combinations with PMR-AS values lower 7, all but 3 (0.5%) had no relapse diagnosis. Of 510 combinations with PMR-AS values of 7 or more, only 42 (8%) had no flare diagnosis.

**Conclusions:** This study supports the validity of PMR-AS in primary care practice and provides evidences that a good scoring system can be useful to guide clinical and therapeutic decisions.

**Keywords:** Disease activity score. PMR-AS. Polymyalgia rheumatica. Sensitivity. Specificity. General practitioners. Corticosteroids. Flare. Relapse.

Polymyalgia rheumatica (PMR) is an inflammatory joint disease of the elderly characterized by pain and morning stiffness in the neck and limb girdles with elevation of laboratory markers for inflammation including the erythrocyte sedimentation rate (ESR) and serum C-reactive protein level (CRP). Long-term corticosteroid therapy is the cornerstone of the treatment of PMR, and low dosages (10 to 20 mg prednisone/day) are often sufficient to correct the clinical symptoms and laboratory evidence of inflammation within a few days. The dosage is then tapered according to disease activity as assessed using a combination of clinical symptoms and ESR and/or CRP (1). Many patients can be tapered off glucocorticoid therapy after 1 to 2 years. However, relapses may occur, requiring glucocorticoid dosage increases, so that 50% of patients are still on treatment after 2-3 years or more (2). Long-term corticosteroid exposure in elderly patients, many of whom have co-morbid conditions, often generates adverse effects. In a database study, patients receiving treatment for PMR had a 2.5-fold increase in the risk of diabetes mellitus, vertebral fractures, femoral neck fractures, and hip fractures, compared to the same-age general population (3). Furthermore, increases have been reported in the risk of myocardial infarction, heart failure, peripheral vascular disease, and cerebrovascular disease. Although this increased cardiovascular risk may be related to long-term inflammation rather than to glucocorticoid therapy (4), carefully tailoring the glucocorticoid dosage to the patient's needs is crucial in order to strike the best compromise between the risk of treatment-related adverse effects and the risks associated with uncontrolled inflammation.

Leeb and Bird (5) developed a disease activity score for PMR (PMR-AS), which is computed by summing five parameters: morning stiffness (MST, in minutes, multiplied by 0.1 for weighting purposes), ability to elevate the upper limbs (EUL, on a scale from 0 to 3), physician's global assessment using a 10-point visual analog scale (VASph), pain measured

by the patient using a 10-point visual analog scale (VASp), and the C-reactive protein level (CRP, in mg/dl). PMR-AS values lower than 7 indicated low disease activity, values between 7 and 17 moderate disease activity, and values greater than 17 high disease activity (Figure 1). PMR-AS is well-suited to everyday practice, and its usefulness has been further improved by the determination of cut-offs for disease remission and relapse. Thus, PMR-AS values between 0 and 1.5 suggested disease remission (6) and values greater than 9.35 (in patients with previously controlled disease) or having increased by 6.6 or more between two visits suggested disease relapse (7). Studies consistently found that the PMR-AS was easy to use and valid when determined by rheumatologists (5-8), despite considerable interobserver variability in the VASp score, the only subjective component of the PMR-AS. However, general practitioners (GPs) play a major role in the management of patients with PMR. In a population-based cohort of PMR patients, the mean number of GP visits per person-year of follow-up was 7.0 during the first year (versus 2.2 for rheumatologist visits) and 3.8 during the second year (versus 0.8 for rheumatologist visits) (9); 39.6% of patients were managed only by GPs and 28% had a single rheumatologist visit. Therefore, the feasibility and validity of PMR-AS determination by GPs needed to be evaluated.

In an earlier study (8) based on a previously established methodology (10,11), we asked a panel of rheumatologists to assess nine fictional scenarios, with the goal of assessing the impact of VASp interobserver variability on PMR-AS values and the effectiveness of PMR-AS in predicting glucocorticoid dosage changes and relapse diagnosis. For seven of the nine clinical vignettes, at least 80% of the rheumatologists agreed on a diagnosis of relapse or no relapse. Furthermore, despite interobserver variability in VASp scores, a PMR-AS value greater than 7 was 98.1% sensitive and 94.3% specific for a diagnosis of relapse requiring a glucocorticoid dosage increase.

The objective of this study was to evaluate the feasibility and validity of PMR-AS determination by GPs. More specifically, we sought to determine whether VASp scores determined by GPs were equivalent to those determined by rheumatologists. We also evaluated whether the PMR-AS score computed using the GP-assessed VASp correlated with a diagnosis of relapse or no relapse by the rheumatologists, which served as the reference standard. To this end, we used the seven clinical vignettes that generated strong agreement among rheumatologists about a diagnosis of relapse or no relapse in our previous study (8). These vignettes were evaluated by 163 GPs.

## Methods

### *Clinical vignettes*

Nine clinical vignettes (Table 1) describing fictional patients with PMR were written by a panel of rheumatologist experts who were members of the Inflammatory Joint Disease Working Group of the French Society for Rheumatology (Club "Rhumatismes et Inflammation"). The vignettes spanned the full spectrum of disease-activity levels. They shared common features: a definitive diagnosis of PMR; initial symptoms consisting of asthenia, anorexia, weight loss, limited active range of motion of the shoulders, and aching and morning stiffness in the neck and limb girdles; elevated ESR and CRP; a rapid response to prednisone therapy with complete resolution of clinical symptoms and normal ESR and CRP; and initial prednisone therapy in a dosage of 0.3 mg/kg/day for 15 days and 0.25 mg/kg/day for the next 15 days, then 0.2 mg/kg per day followed by tapering every week or 2 weeks for about 6 months. Recurrence of clinical symptoms or ESR or CRP elevation was described in the vignettes as suggestive of a relapse.

### *Reference standard for the diagnosis of relapse*

In a previous study (8), the nine vignettes were submitted to 35 office- and hospital-based rheumatologists who were asked to decide whether the disease was relapsing. For the

present study, we used the vignettes for which at least 28 (80%) rheumatologists agreed that the disease was or was not relapsing, in keeping with the methodology used in previous studies based on questionnaires or clinical vignettes (10, 11). Seven of the nine vignettes met this criterion. (For the remaining two vignettes, 43% and 60% of the rheumatologists, respectively, felt that there was no relapse.)

#### *Study design*

The seven vignettes were submitted to 163 GPs, who were asked to determine the VASph score and to decide whether the disease was relapsing and whether a prednisone dosage increase was in order. The GPs also completed a questionnaire designed to evaluate their experience with managing PMR patients (based on the number of patients followed up for PMR over the last year) and their opinions about the need for rheumatologist visits for the diagnosis of PMR and/or the follow-up of PMR patients, most notably in the event of glucocorticoid dependency or side effects. Data on relapse diagnosis were obtained for 1116 vignette-GP combinations (158 for vignettes 1 and 4; 159 for vignette 2; 160 for vignettes 3, 5, and 7; and 161 for vignette 6). Among them, the GPs' opinions about the glucocorticoid dosage were available for 1106 combinations, 1100 had VASph values assessed by the GPs. The PMR-AS was computed for these 1100 combinations with complete data, and its performance for relapse diagnosis was evaluated.

#### *Statistical analysis*

Results for the quantitative variable VASph are reported as the means $\pm$ SD and those for the qualitative variables (diagnosis of relapse and decision to increase the prednisone dosage) as percentages and as number of "yes" answers for each vignette.

We computed the PMR-AS as indicated by Leeb and Bird (5): PMR-AS = CRP (mg/dl) + VASp (0-10) + VASph (0-10) + (MST(min) $\times$ 0.1) + EUL (0-3). The four levels on the semi-quantitative EUL scale are as follows: 3, no upper limb elevation; 2, elevation below the shoulder girdle ( $<90^\circ$ ); 1, elevation up to the shoulder girdle ( $90^\circ$ ); and 0, elevation above the shoulder girdle ( $>90^\circ$ ) (Figure 1). Patient groups were compared using the Chi-square ( $\chi^2$ ) test for qualitative variables and the Mann-Whitney U test for quantitative variables. *P* values smaller than 0.05 were considered statistically significant.

We studied the associations linking a diagnosis of relapse by the panel of rheumatologists (the reference standard) with the values of the PMR-AS based on the GP-assessed VASph and with each of its five components (MST, EUL, GP-assessed VASph, VASp, and CRP). Receiver-operating characteristic (ROC) curves were plotted. Sensitivities and specificities were calculated at different cut-off values. The optimal cut-off for a variable was defined as the value nearest the northwest point of the ROC curve. When two similar cut-off values were found, the one with the best sensitivity was chosen. Statistical tests were performed using the Statistical Package for the Social Sciences (SPSS 13.0, 2007, SPSS Inc, Chicago, IL).

## **Results**

### *Experience and opinions of GPs regarding the management of PMR*

The mean number of patients with PMR followed in 2006 was  $2.52\pm 2.48$  [0-20] per GP. Only 35.8% (57/159) of the GPs routinely referred patients to the rheumatologist to confirm the diagnosis and only 19.9% (32/161) felt that routine follow-up by a rheumatologist was required. Conversely, in the event of a relapse or glucocorticoid dependency, 41.3% (66/160) and 63.1% (101/160) of GPs, respectively, felt that prompt rheumatologist referral was appropriate. Side effects of glucocorticoid therapy were felt to indicate a need for rheumatologist referral by only 31% (49/158) of the GPs. Finally, 41.7% (58/139) of the GPs

reported that some of their patients with PMR had no rheumatologist visits throughout the course of their disease (from diagnosis to full recovery).

#### *Agreement between relapse diagnosis by GPs and by rheumatologists*

Relapse diagnosis by GPs correlated closely with relapse diagnosis by rheumatologists, which was used as the reference standard. Agreement was 90.3% [95% confidence interval (95CI), 88.4-91.9%] with  $\kappa=0.80$ . Of the 504 relapse diagnoses made by GPs, 67 (13.3%) cases had no relapse diagnosis by rheumatologists; and of 612 diagnoses of non-relapsing disease made by GPs, 41 (6.7%) had a relapse diagnosis by rheumatologists.

#### *Diagnosis of relapse and decision to increase prednisone*

As expected, we found a significant ( $P<0.001$ ) association between diagnosing a relapse and deciding to increase the prednisone dosage, with an agreement of 95.1% [95CI, 93.6-96.3%]. Of 1106 vignette-GP combinations, 1052 were concordant for the GP diagnosis of relapse and the decision to increase prednisone, including 416 assigned to both the "relapse" group and the "increase prednisone dosage" group and 576 to both the "no relapse" group and the "do not increase prednisone dosage" group. 32 patients assigned to the "no relapse" group were assigned to the "increase prednisone dosage" group, and the opposite occurred for 22 patients.

#### *Diagnostic impact of clinical and laboratory parameters*

As expected, interobserver variability was noted in physicians' assessments of disease activity (the VASph component of the PMR-AS). Thus, the mean $\pm$ SD and ranges for GP-determined VASph scores for vignettes 1 through 7 were 1.95 $\pm$ 1.40 (0-10), 1.66 $\pm$ 1.00 (0-6), 3.88 $\pm$ 1.65 (1-10), 4.48 $\pm$ 1.88 (0-10), 2.03 $\pm$ 1.17 (0-8), 1.81 $\pm$ 1.22 (0-8), and 4.23 $\pm$ 1.87 (0-10), respectively (Figure 2). Nevertheless, no significant difference was found between GP and rheumatologist VASph scores (Table 1).

Figure 3 shows the ROC curves of associations linking relapse diagnosis by the rheumatologists (the reference standard) to the PMR-AS and each of its components (MST, EUL, GP-assessed VASph, VASp, and CRP) for the seven vignettes used in the study. Table 2 shows the best cut-off values for the better-performing parameters, together with their sensitivities and specificities. MST longer than 10 minutes was 100% sensitive and 100% specific. Relapse diagnosis was strongly associated with PMR-AS  $\geq 7$ , which was 99.4% sensitive and 93.3% specific. Performance was somewhat lower for VASph  $\geq 2.5$  (88.5% sensitive and 78.9% specific) and CRP  $\geq 14.5$  mg/L (66.5% sensitive and 100% specific). EUL and VASp showed weaker associations with relapse diagnosis (VASp  $\geq 1.5$ , 100% sensitive and 59.1% specific; EUL  $\geq 1$ , 66.5% sensitive and 75.0% specific).

#### *Agreement between relapse diagnosis by rheumatologists and relapse diagnosis defined as GP-based PMR-AS $\geq 7$*

PMR-AS values correlated closely with relapse diagnosis: agreement was 95.9% [95CI, 94.5-97.0%] for  $\kappa=0.92$ . Of the 590 combination with PMR-AS values lower than 7, all but 3 (0.5%) had no relapse diagnosis. Of 510 combinations with PMR-AS values greater than or equal to 7 (8%), 42 had no flare diagnosis.

## **Discussion**

The PMR-AS, which was developed based on EULAR response criteria for PMR defined by the European Collaborating Polymyalgia Rheumatica Group (12), is a composite index that appears well suited to everyday practice and useful for tailoring glucocorticoid dosages to the changing needs of individual patients over time, thereby limiting unnecessary exposure to both glucocorticoids and inflammation. Reports of proposed PMR-AS thresholds for defining remission and relapse (6, 7) may further increase the usefulness of the score in determining when disease control is adequate and when the glucocorticoid dosage should be increased or decreased.

We found excellent agreement (90.3%) between relapse diagnosis by GPs and relapse diagnosis by rheumatologists, as well as between relapse diagnosis by GPs and a decision by GPs to increase the glucocorticoid dosage (95.1% of agreement). Our results on the contribution of GPs to the management of patients with PMR in Brittany, France, are consistent with those obtained in Minnesota, USA (9): thus, less than 40% of GPs routinely referred their patients to the rheumatologist to confirm the diagnosis or to assist in monitoring the treatment. The main reasons for rheumatologist referrals were atypical PMR with glucocorticoid dependency and difficulty in ruling out differentials such as late-onset rheumatoid arthritis and chondrocalcinosis.

The physician's overall assessment of disease activity on a subjective VAS (VASph) varied widely among the 163 GPs for a given vignette (Table 1). Nevertheless, for none of the vignettes was a significant difference found between the mean VASph values determined by the GPs and by the rheumatologists. Moreover, PMR-AS values computed using GP-assessed VASph scores were highly sensitive and specific for a relapse diagnosis by rheumatologists (our reference standard). The best cut-off was also 7 points in our previous study using the same vignettes evaluated by rheumatologists (8). Thus, as reported previously, a global estimate by the physician should not be the sole basis for making treatment decisions (8).

The PMR-AS determined by GPs is a valid tool that would probably help GPs monitor and adjust glucocorticoid regimens in patients with PMR. Both the shortage of rheumatologists and the predominant contribution of GPs to the management of PMR patients lend considerable importance to these findings. Of 590 GP-vignette combinations with PMR-AS values lower than 7, all but 3 had no relapse diagnosis. However, of 510 combinations with PMR-AS values of 7 or more, 42 had no relapse diagnosis. Therefore, referral to a rheumatologist appears unnecessary when the PMR-AS value does not indicate a relapse but may be in order to confirm a relapse when the PMR-AS suggested disease flare. Nevertheless, the percentage of patients managed by GP's or rheumatologist differ from country to another and propositions for referral of patients to rheumatologists should be made in this respect.

Our study has several limitations. First, although the vignettes were written by rheumatologists who had extensive experience with PMR, and the use of clinical vignettes was validated previously (8,11,13), they did not describe real patients. Indeed, the VASph scores assessed by GP's in this study, and compare to specialist's one, were based on hard data only instead of seeing and assessing real patients where the subjective impression and experience is very important and may influence physicians judgment of VASph parameter. This fact support the necessity to complete the validation of PMR-AS used by GP's in real life, all the more that the number of patient managed by GP is quite low, to know whether PMR patients could be well managed by GPs and do not need further specialist's referral. Second, changes in the parameters from one visit to the next were small, except for morning stiffness (MST). This may explain in part why MST was the best variable for diagnosing a relapse. Indeed, in our experience medical practitioners mainly rely on girdle pain and inflammatory markers rather than on morning stiffness to assess disease activity and diagnose a relapse. The morning stiffness appears less important than the other parameters for appreciate disease activity. Moreover, an early morning stiffness shorter than 30 minutes could not discriminate relapses from stable disease in real cases and a short-lived morning stiffness is not relevant. The diagnosis value and the cut-off of 10 minutes find for morning stiffness is likely to be an artefact due to the way the vignettes were designed. A set of vignettes describing larger variations in other parameters might produce slightly different results from these reported here.

The aim of this study was not to define a PRM-AS cut-off indicating a relapse, which was done previously in a prospective study (7), but to establish that the PMR-AS remains valid when used by GPs, i.e., performs as well for diagnosing a relapse when used by GPs as when used by rheumatologists. The external validation of relapse diagnosis by rheumatologists obtained from our study of GP-assessed VASph values strongly supports the usefulness of the PMR-AS in primary care practice. Nevertheless, the agreement between Rheumatologist and GPs could be lower in not typical cases of PMR and it is unclear how well the scoring system would perform in a situation characterized by pitting oedema or by synovitis as the only manifestations of relapse. It is here probably a weakness of the scoring system.

To definitively establish the usefulness of PMR-AS for managing glucocorticoid tapering by GPs in patients with PMR, a prospective cohort study with the relapse rate and total glucocorticoid dosage as the main evaluation criteria is needed. The PMR-AS may be a useful reference standard in future clinical trials to ensure uniformity across study centers or physicians, and is simple enough to be used on an everyday basis by GPs.

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**Table 1.** Main clinical symptoms and laboratory test results in seven clinical vignettes of PMR for which at least 80% of 35 rheumatologists agreed on a diagnosis of relapse or no relapse. These seven vignettes were submitted to 163 general practitioners. The table lists the vignettes in the order of increasing percentage of rheumatologists diagnosing a relapse.

Vignettes (n=7)	#6	#2	#1	#5	#3	#7	#4
<b>Last Visit</b>							
VASph (0-10)	1	2	1	4	2	1	1
MST (min)	0	0	0	20	10	0	0
EUL (°)	120	120	90	90	120	180	120
CRP (mg/L)	7	9	9	18	10	7	10
VASp (0-10)	1	1	1	3	1	0	1
Prednisone (mg/d)	5	12	11	15	14	5	12
<b>Current visit</b>							
Visit	SV	ER	ER	SV	SV	ER	SV
Symptoms	Pain	Asthenia	Asthenia	Asthenia	-	MST	-
VASp (0-10)	3	1	1	2	2	3	3
MST (min)	0	0	0	0	20	10	20
EUL (°)	160	180	90	120	90	120	90
CRP (mg/L)	7	12	12	8	17	12	20
<b>Rheumatologists' diagnoses</b>							
Percentage of the 35 rheumatologists giving a relapse diagnosis	0	6	11	11	91	97	100
Relapse yes/no	No	No	No	No	Yes	Yes	Yes
Mean VASph±SD*	1.50±0.7	1.87±0.7	2.01±1.1	2.14±1.3	4.18±1.5	4.04±1.7	4.70±1.8
<b>GPs' diagnoses</b>							
Percentage of the 163 GPs giving a relapse diagnosis	6	9	23	5	87	95	92
Percentage of the 163 GPs deciding to increase the prednisone dosage	14	10	27	5	83	93	92
Mean VASph±SD*	1.81±1.2	1.66±1.0	1.95±1.4	2.03±1.2	3.88±1.6	4.23±1.9	4.48±1.9

GPs: general practitioners; SV: scheduled visit; ER: emergency room visit; MST: morning stiffness; EUL: elevation of upper limbs; VASph: global assessment of disease activity by the general practitioners; VASp: pain measured on a 0-10 visual analog scale; CRP: serum C-reactive protein level; SD: Standard deviation.

\* No statistical difference between VASph scores for a given vignette.

**Table 2.** Optimal cut-offs for the PMR-AS and each of its components, with their sensitivities and specificities, for diagnosing relapses of polymyalgia rheumatica.

	Sensitivity %	Specificity %
MST $\geq$ 10 minutes	100	100
PMR-AS $\geq$ 7	99.4	93.3
VASph $\geq$ 2.5	88.5	78.9
CRP $\geq$ 14.5 mg/L	66.5	100
VASp $\geq$ 1.5	100	50.1
EUL $\geq$ 1	66.5	75.0

MST, morning stiffness; PMR-AS: polymyalgia rheumatica activity score; VASph, global assessment of disease activity by the general practitioners; CRP, serum C-reactive protein level; VASp, pain measured on a 0-10 visual analog scale; EUL, elevation of upper limbs

### Figure legends

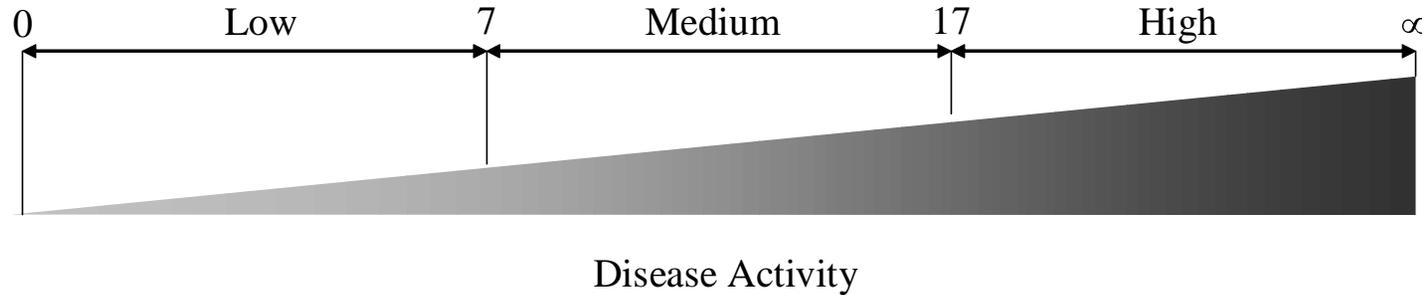
**Figure 1.** The polymyalgia rheumatica activity score (PMR-AS) in everyday practice  
MST: morning stiffness duration; VASph: physician's global assessment on a 0-10 visual analog scale; CRP: serum C-reactive protein level; VASp: pain severity on a 0-10 visual analog scale; EUL: elevation of upper limbs.

**Figure 2.** Box-and-whisker plots of global assessments (VASph) by general practitioners (GPs) for each of the seven vignettes. VASph was evaluated on a 0-10 visual analog scale.

**Figure 3.** Receiver-operating characteristic curves of associations linking relapse diagnosis to PMR-AS and each of its components (morning stiffness, ability to elevate upper limbs, global assessment by general practitioners, visual analog scale for pain, and C-reactive protein level. MST: morning stiffness; PMR-AS: activity score for polymyalgia rheumatica; VASph: global assessment by general practitioners on a 0-10 visual analog scale; CRP: serum C-reactive protein level; VASp: pain severity on a 0-10 visual analog scale; EUL: elevation of upper limbs.

**Figure 1.** The polymyalgia rheumatica activity score (PMR-AS) in everyday

$$\text{PMR-AS} = \text{VASp (0-10)} + \text{VASph (0-10)} + \text{CRP (mg/dl)} + (\text{MST(min)} \times 0.1) + \text{EUL (0-3)}$$



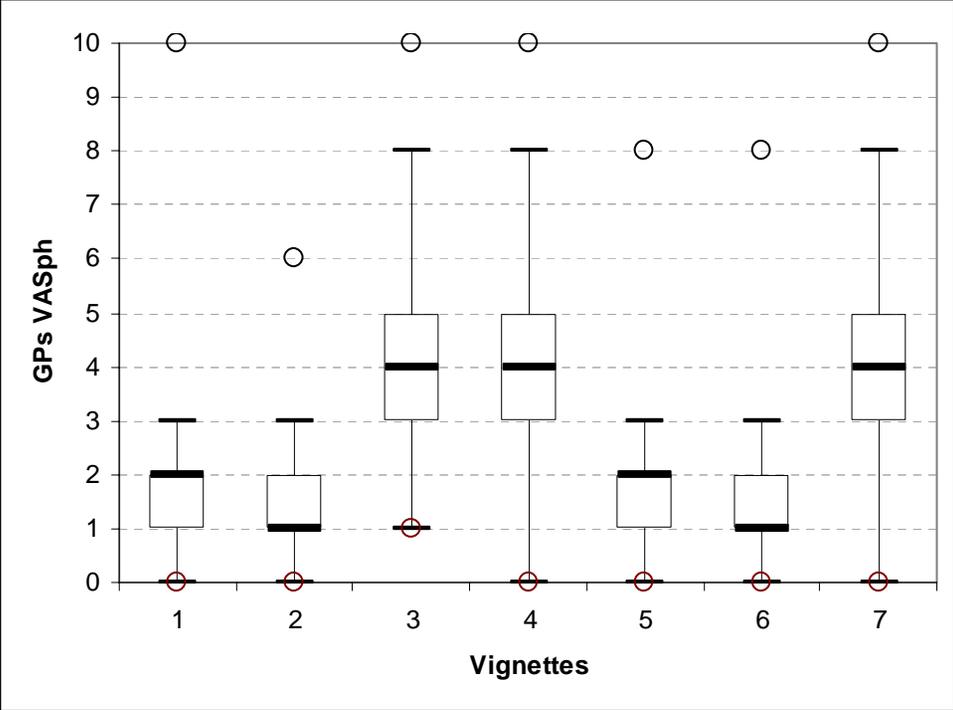
Proposed definition of remission (6): PMR-AS values [0 - 1.5]

Proposed definition of relapse (7):

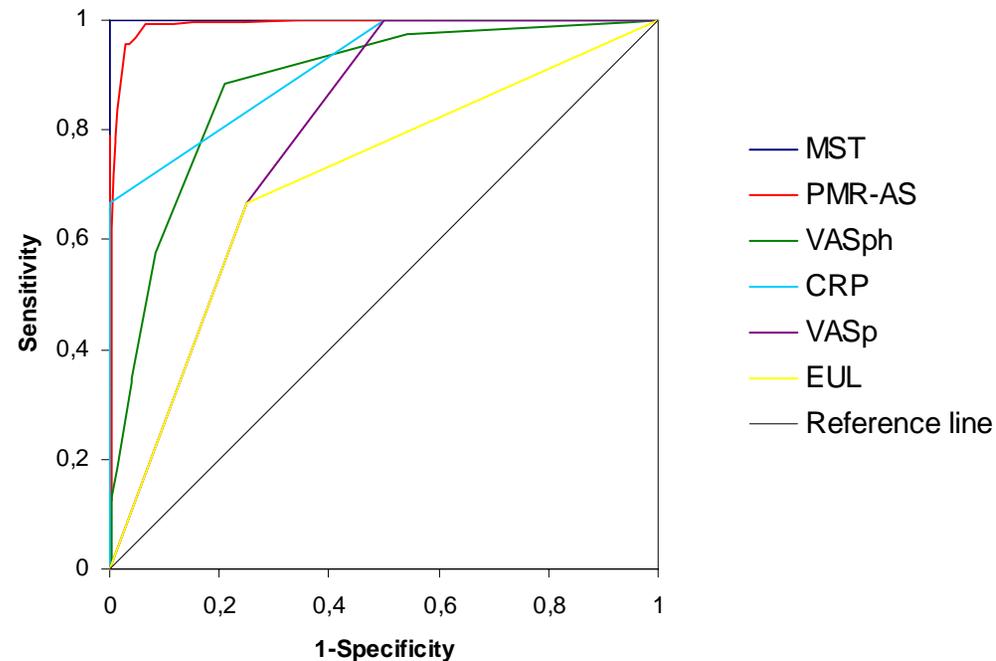
- PMR-AS  $\geq 9.35$  (if the disease was previously controlled)
- $\Delta\text{PMR-AS} \geq 6.6$  ( $\Delta\text{PMR-AS}$ , magnitude of change in PMR-AS between two visits)

MST: morning stiffness duration; VASph: physician's global assessment on a 0-10 visual analog scale; CRP: serum C-reactive protein level; VASp: pain severity on a 0-10 visual analog scale; EUL: elevation of upper limbs.

**Figure 2.** Box-and-whisker plots of physicians' global assessments (VASph) by general practitioners (GPs) of each of seven vignettes. VASph was evaluated on a 0-10 visual analog scale.



**Figure 3.** Receiver-operating characteristic curves of associations linking relapse diagnosis by rheumatologists (the reference standard) to PMR-AS and each of its components (morning stiffness, ability to elevate upper limbs, global assessment by the general practitioners, visual analog scale for pain, and C-reactive protein level).



MST: morning stiffness; PMR-AS: activity score for polymyalgia rheumatica; VASph: global assessment by general practitioners on a 0-10 visual analog scale; CRP: serum C-reactive protein level; VASp: pain severity on a 0-10 visual analog scale; EUL: elevation of upper limbs.