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External validation of the polymyalgia rheumatica impact scale: a prospective cohort study

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Abstract

Objectives: To externally validate the PMR impact scale (PMR-IS).

Methods: We conducted a prospective cohort study at the University Hospitals Leuven, Leuven, Belgium. Recently diagnosed PMR patients were included between July 2022 and December 2023 and followed until 1 year after diagnosis. All patients completed the PMR-IS, HAQ Disability Index, 36-item Short Form and a visual analogue scale for pain at every visit. Internal consistency, floor and ceiling effects, construct validity, responsiveness and discriminatory power for detecting relapse on the PMR-IS were assessed.

Results: Fifty-five PMR patients (mean age 71 years, 47% female) were included, who had a total of 246 visits. Internal consistency, construct validity and responsiveness met the quality criteria for the symptoms, function and emotional and psychological well-being subdomains. The internal consistency of the glucocorticoid side effects subdomain was insufficient and only one of the three hypotheses for construct validity were met. The function and emotional and psychological well-being subdomains showed a floor effect, while no ceiling effect was observed. The symptoms, function and emotional and psychological well-being subdomains had a good discriminatory power for detecting relapse [area under the curve (AUC) 0.89, 0.86 and 0.72, respectively], but the PMR activity score performed better (AUC 0.94, $P < 0.05$ for all subdomains).

Conclusion: This study validates the good measurement properties of the symptoms, function and emotional and psychological well-being subdomains of the PMR-IS. In contrast, the glucocorticoid side effects subdomain did not show adequate internal consistency and construct validity, necessitating further validation and possibly refinement of its items prior to application in clinical trials or daily practice.

Lay Summary

What does this mean for patients?

Polymyalgia rheumatica (PMR) is an inflammatory disease characterized by pain and morning stiffness in the shoulders, pelvic girdle and neck. The PMR impact scale (PMR-IS) is a recently developed questionnaire that allows patients to report how PMR affects their daily life. This study validates the PMR-IS in a distinct patient cohort. Researchers followed 55 patients with a recent diagnosis of PMR for 1 year, evaluating different aspects of the scale, including its reliability, validity, responsiveness and ability to detect disease relapse. The study found that the symptoms, function and emotional and psychological well-being subdomains of the scale performed well, showing good reliability, validity and responsiveness. These subdomains also effectively identified PMR relapses. However, the glucocorticoid side effects subdomain did not meet the required quality criteria, suggesting the need for further improvement. Overall, the PMR-IS is a useful tool for measuring the impact of PMR on patients' lives from the patient's perspective, but refinements are needed, particularly for assessing glucocorticoid side effects, before widespread use in research or clinical practice.

Keywords: polymyalgia rheumatica, PMR, PMR impact scale, patient-reported outcome measure.

Key messages

- The symptoms, function and emotional and psychological well-being subdomains of the PMR impact scale had good internal consistency, construct validity and responsiveness.
- The function and emotional and psychological well-being subdomains showed a floor effect.
- The glucocorticoid side effects subdomain did not show adequate internal consistency and construct validity, necessitating further validation and possibly refinement of the items prior to application in clinical trials and daily practice.

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Introduction

PMR is a systemic inflammatory disease characterized by pain and morning stiffness in the shoulders, pelvic girdle and neck. It predominantly affects individuals >50 years of age and is often associated with constitutional symptoms and elevated inflammatory markers [1]. Glucocorticoids remain the standard treatment, but there are still many unanswered questions about the optimal management of PMR. Prednisone in a daily dose of 12.5–25 mg generally results in quick resolution of symptoms and inflammation [2]. However, about half of PMR patients experience disease relapse during tapering or shortly after stopping treatment with glucocorticoids [3]. This requires restarting or increasing the glucocorticoid dose, increasing the notorious glucocorticoid-associated side effects. High-quality evidence on the optimal duration of glucocorticoid treatment and glucocorticoid-sparing agents is urgently needed. However, the lack of reliable, valid and sensitive outcome measures hampers the evaluation of such studies.

OMERACT facilitates the development of core outcome sets for autoimmune and musculoskeletal diseases by identifying patient- and disease-relevant domains along with appropriate measurement instruments for clinical trials [4]. Based on a Delphi study with physicians and patients, OMERACT identifies four inner core domains that are mandatory for clinical trials of PMR: pain, stiffness, physical function and laboratory markers of systemic inflammation. These domains are most frequently assessed using the following measures: a visual analogue scale for pain (VASp), morning stiffness duration for stiffness, HAQ Disability Index (HAQ-DI) for physical function and CRP and/or ESR for systemic inflammation [5–7]. Patient's global fatigue was strongly recommended to be measured in PMR as well [5]. However, outcome measures in PMR studies lack consistency and there is limited evidence regarding their measurement properties to justify their use in PMR [6].

Patient-reported outcome measures (PROMs) are increasingly acknowledged as reliable and sensitive tools for evaluating outcomes across a wide range of conditions [8]. In clinical trials and observational studies, incorporating PROMs alongside traditional clinical indicators provides a structured way to capture the patient's perspective on the physical, functional and psychological impacts of the disease, thereby enabling a more holistic assessment of interventions or the evolution of the disease. In clinical practice, PROMs offer valuable insights at an individual level, aiding in patient assessment, treatment decisions, follow-up scheduling and supporting self-management [8, 9]. PROMs allow patients to share their experiences, evaluate whether treatment meets their expectations and identify unmet needs or areas for improvement [8, 9]. Given the symptoms of PMR, the lack of a comprehensive objective measure for disease activity and the need to balance treatment with potential side effects, PMR is particularly well-suited for patient-reported assessments.

Recently a PMR-specific PROM was developed, called the PMR impact scale (PMR-IS). First, a qualitative study was carried out to explore patient experiences and to develop a conceptual framework [10]. Afterwards, a long list of candidate items for the PROM was developed and the face validity, feasibility and utility were tested in a small number of patients [11]. Subsequently the questionnaire was further refined in a large cohort by assessment of item response distribution, exploratory factor analysis, Rasch analysis and patient and professional feedback, after which the measurement properties of the final scale structure were tested [12]. The final PMR-IS consists of four subdomains: symptoms, physical functioning, emotional and psychological well-being and glucocorticoid side effects. To date, this questionnaire has not been externally validated in a distinct patient cohort. In addition, the original study asked patients to retrospectively complete the questionnaire, thinking back to how they felt at the time of diagnosis, which carries a high risk of recall bias and bias due to response shift [12]. The aim of this study was to further validate the PMR-IS in a prospective cohort of patients with recently diagnosed PMR.

Methods

Patient population

We prospectively included all consecutive patients with a recent diagnosis of PMR (within 8 weeks), who were evaluated by the Department of General Internal Medicine or Rheumatology of the University Hospitals Leuven, Leuven, Belgium, between July 2022 and December 2023. Patients were followed until 1 year after diagnosis. Patients who were unable to understand and write Dutch or English, patients with a concomitant diagnosis of GCA, concurrent RA, other inflammatory arthritis or CTD or patients treated with glucocorticoids or other immunosuppressive drugs for another indication were excluded. The final diagnosis of PMR was based on the judgment of the treating physician, considering all available information (clinical data, biochemical and radiological results and evolution during follow-up). The treatment was at the discretion of the treating physician.

The study was conducted in accordance with the Declaration of Helsinki and approved by the ethical committee of UZ Leuven (S66638). All patients gave their informed consent.

Translation and adaptation of the PMR-IS

We cross-culturally adapted and translated the PMR-IS into Dutch. First, a native Dutch-speaking translator forward-translated the English PMR-IS into Dutch. Then, the questionnaire was back-translated into English by a bilingual translator, who had no medical training. The translated version was reviewed alongside the original PMR-IS in a group to identify any inconsistencies. Next, five Dutch-speaking PMR patients tested the Dutch version of the PMR-IS to evaluate its comprehensibility. The Dutch and English version of the PMR-IS can be found in Supplementary Data S1, available at *Rheumatology Advances in Practice* online.

Data collection

All patients completed the PMR-IS, HAQ-DI and 36-item Short Form Health Survey (SF-36) questionnaires at every visit in the waiting room without guidance from study personnel. The PMR-IS assesses four subdomains: symptoms, physical functioning, emotional and psychological well-being and glucocorticoid side effects. The score for each subdomain is the mean item score converted to a percentage. Higher scores (0–100) correspond with greater impact. The score for the glucocorticoid side effects subdomain was only calculated for visits where patients were taking glucocorticoids. HAQ-DI is a self-reported questionnaire with eight domains

reflecting the ability to perform activities of daily living: dressing, arising, eating, walking, hygiene, reach, grip and common daily activities. Higher scores (0–3) indicate worse functional status. The SF-36 is a self-reported questionnaire with eight domains: four physical domains (physical functioning, bodily pain, role limitations due to physical health problems and general health perceptions) and four emotional and psychological well-being domains (role limitations due to personal or emotional problems, emotional well-being, social functioning and energy/fatigue). Higher scores on the SF-36 domains (0–100) reflect a better perceived health status.

Additionally, all patients completed a horizontal VAS for pain (VASp) at every visit by drawing a vertical line on a horizontal line of 100 mm from 0 (best ever) to 100 (worst ever). The treating physician filled in the duration of morning stiffness (MST; in min), the ability to elevate the upper limbs (EUL; 3 = none, 2 = below shoulder girdle, 1 = up to shoulder girdle, 0 = above shoulder girdle) and the physician's global assessment (VASph; as a horizontal VAS). The PMR activity score (PMR-AS) was calculated as CRP*0.1 (mg/l) + VASp (0–100)*0.1 + VASph (0–100)*0.1 + MST (min)*0.1 + EUL (0–3).

Statistical analysis

Based on conceptual knowledge and data exploration, missingness was considered to be at random and handled with multiple imputation ($m = 20$ imputations). Categorical and continuous variables were expressed as number (percentage) and mean (S.D.) or median [interquartile range (IQR)] as appropriate. The PMR-IS was assessed for floor and ceiling effects by evaluating the frequencies of minimum and maximum responses (significant if >15%) and for internal consistency via Cronbach's α (sufficient if >0.70) [13, 14]. Construct validity was evaluated by assessing the correlation of the subdomains of the PMR-IS with other outcomes via Spearman coefficients. We used the same prespecified hypotheses as in the original study [12]. We added the hypotheses of a moderate ($r > 0.4$) positive correlation between the glucocorticoid side effects subdomain and the glucocorticoid dose and duration.

Responsiveness was evaluated via mean change scores and effect sizes between two visits with stable disease, a visit with active disease followed by a visit in remission and a visit in remission followed by a visit with active disease. Active disease could be a new diagnosis within 7 days of the start of glucocorticoids or relapse. Relapse was defined as a recurrence of clinical symptoms compatible with PMR or GCA and/or an increase in inflammatory markers requiring escalation of treatment. Effect sizes were calculated as the mean change score divided by the pooled S.D. Effect sizes <0.20 were considered trivial, ≥0.20–<0.50 small, ≥0.50–<0.80 medium and ≥0.80 large (or vice versa for negative values) [15]. For the symptoms, function and emotional and psychological well-being subdomains, we expected trivial effect sizes for two visits with stable disease activity. We expected large effect sizes for the symptoms and function subdomains and medium effect sizes for the emotional and psychological well-being subdomain between visits with a change in disease activity. For the glucocorticoid side effects subdomain, responsiveness with change in disease activity is not relevant and was therefore not calculated. The scores of the subdomains of the PMR-IS were compared between visits with active disease and those with disease remission via the Mann–Whitney *U* test. Additionally, discriminatory power for detecting active disease was determined with the area under the receiver operating characteristics (ROC) curve (AUC) and compared with the PMR-AS via Delong's test. The optimal cut-off point was determined by the smallest Euclidian distance to the upper left corner of the ROC curve and the corresponding sensitivity and specificity were calculated. Statistical analysis was performed in R Studio version 2023.04.21 (R Foundation for Statistical Computing, Vienna, Austria).

Results

In total, 55 PMR patients were included. Baseline characteristics are shown in Table 1. These 55 patients had 246 visits in total, of which 63 were for active disease (43 at diagnosis and 20 at relapse). Table 2 provides an overview of inflammatory markers, VASp, PMR-AS, HAQ-DI, SF-36 and PMR-IS scores.

Cronbach's α was 0.96 (95% CI 0.95, 0.97), 0.94 (95% CI 0.93, 0.95) and 0.91 (95% CI 0.88, 0.93) in the symptoms, function and emotional and psychological well-being subdomains, respectively, showing high internal consistency. Cronbach's α was 0.70 (95% CI 0.31, 0.75) in the glucocorticoid side effects subdomain, corresponding with an insufficient internal consistency. In the function and emotional and psychological well-being subdomains, there was a floor effect, with 29% and 33% of patients, respectively, scoring at the minimum (Supplementary Table S1, available at *Rheumatology Advances in Practice* online). A ceiling effect was not present.

Eight of ten hypotheses about correlations between the symptoms, function and emotional and psychological well-being subdomains of the PMR-IS and other relevant questionnaires were met, indicating good construct validity (Table 3). However, only one-third of the hypotheses about the glucocorticoid side effects subdomain were satisfied.

All nine hypotheses about responsiveness were satisfied (Table 4). The effect sizes were trivial in case of stable disease and were medium for the emotional and psychological well-being subdomain and large for the symptoms and function subdomains in case of a change in disease activity. Table 2 provides an overview of the scores of the subdomains for

Table 1. Baseline characteristics of included patients ($N = 55$).

Test characteristics	Values
Age, years, mean (S.D.)	71 (9)
Female, *n* (%)	26 (47)
Symptoms at diagnosis, *n* (%)	
Morning stiffness > 45 min	42 (76)
Bilateral shoulder pain	49 (94)
Pelvic girdle pain	45 (82)
Neck pain	24 (44)
Lower back pain	14 (25)
Pain in peripheral joints, *n* (%)	18 (33)
Peripheral arthritis	8 (15)
Laboratory tests at diagnosis	
Abnormal CRP and/or ESR, *n* (%)	53 (96)
CRP, mg/l, median (IQR)	21 (11–49)
ESR, mm/h, median (IQR)	25 (16–36)
Negative RF and/or ACPA, *n* (%)	45 (100)[10]
Negative RF	43 (98)[11]
Negative ACPA	40 (100)[15]

Number of missing values are reported as superscripts.

Table 2. Overview of the inflammatory markers, VASp, PMR-AS and HAQ-DI, SF-36 and PMR-IS scores for visits with active disease and visits in remission

Test characteristics, median (IQR)	Total ($N = 246$)	Active disease ($n = 63$)	Remission ($n = 183$)	*P*-value
Disease duration, months	4 (1–8)	0 (0–4)	5 (2–9)	**<0.001**
Methylprednisolone dose, mg	4 (1–8)	0 (0–2)	4 (2–8)	**<0.001**
CRP, mg/l	2 (1–7)	15 (4–34)	2 (1–4)	**<0.001**
ESR, mm/h	10 (4–16)	22 (11–29)	8 (4–12)	**<0.001**
VASp (0–100)	23 (8–51)	65 (45–76)	14 (6–30)	**<0.001**
PMR-AS	6 (2–18)	26 (18–35)	3 (2–8)	**<0.001**
HAQ-DI (0–3)	0.50 (0–1.25)	1.25 (0.88–1.88)	0.38 (0.00–0.88)	**<0.001**
SF-36 (0–100)				
Physical functioning	75 (45–90)	50 (25–70)	80 (65–90)	**<0.001**
Bodily pain	62 (41–84)	32 (22–51)	74 (52–84)	**<0.001**
Role limitations due to physical health problems	50 (0–100)	0 (0–25)	75 (0–100)	**<0.001**
General health perceptions	60 (45–72)	55 (40–62)	62 (47–77)	**0.004**
Role limitations due to personal and emotional problems	100 (33–100)	67 (0–100)	100 (67–100)	**0.002**
Emotional well-being	76 (60–84)	64 (52–800)	76 (68–88)	**<0.001**
Social functioning	75 (50–100)	63 (38–88)	88 (63–100)	
Energy/fatigue	60 (45–75)	50 (40–60)	67 (50–80)	**<0.001**
PMR-IS (0–100)				
Symptoms	31 (11–55)	65 (52–77)	19 (6–39)	**<0.001**
Function	22 (0–44)	56 (39–72)	11 (0–28)	**<0.001**
Emotional and psychological well-being	13 (0–38)	38 (13–50)	13 (0–25)	**<0.001**
Glucocorticoid side effects[a]	18 (7–30)	20 (17–33)	17 (7–30)	0.095

[a] The glucocorticoid side effects domain was only calculated in patients who were taking glucocorticoids. A score for this subdomain was available for 190 visits, of which 23 had active disease and 167 remission.
Significant values in bold.

Table 3. Hypotheses testing for construct validity.

Comparator construct	Hypotheses	Results (Spearman correlation)	Interpretation
Symptoms	The symptoms score of the PMR-IS is moderately to highly negatively correlated ($r < -0.5$) with the bodily pain and energy/fatigue scores of the SF-36	−0.89 with SF-36 bodily pain, −0.62 with SF-36 energy/fatigue	2 of 2 hypotheses met
Physical function	The score from the function subdomain on the PMR-IS is strongly positively correlated ($r > 0.6$) with the score on the HAQ-DI and strongly negatively correlated with the physical functioning, social functioning and role limitation physical scores of the SF-36 ($r < -0.6$)	0.87 with the HAQ-DI, −0.82 with SF-36 physical functioning, −0.52 with SF-36 social functioning, −0.68 with SF-36 role limitation physical	3 of 4 hypotheses met
Emotional and psychological well-being	The score from the emotional and psychological well-being subdomain of the PMR-IS is strongly negatively correlated ($r < -0.6$) with the emotional well-being, social functioning and role limitation emotional scores of the SF-36	−0.65 with SF-36 emotional well-being, −0.65 with SF-36 social functioning, −0.58 with SF-36 role limitation emotional	2 of 3 hypotheses met
Glucocorticoid side effects	The score from the glucocorticoid side effects subdomain of the PMR-IS score correlates negatively ($r < -0.2$) with the general health scores of the SF-36 and moderately ($r > 0.4$) with the glucocorticoid dose and duration	−0.55 with SF-36 general health, −0.05 with glucocorticoid dose, 0.06 with glucocorticoid duration	1 of 3 hypotheses met
Symptoms and function—internal relationship	The symptoms score of the PMR-IS correlates positively and moderately strongly ($r > 0.4$) with the function subdomain of the PMR-S	0.77 with function domain of the PMR-IS	Hypothesis met

visits with active disease and visits in remission. As expected, the scores of the symptoms, function and emotional and psychological well-being subdomains were significantly higher in patients with active disease compared with those in remission (65 *vs* 19, 56 *vs* 11 and 38 *vs* 13, respectively; all $P < 0.001$). The symptoms and function subdomains had good discriminatory capacity for active disease [AUC 0.89 (95% CI 0.85, 0.94) and AUC 0.86 (95% CI 0.80, 0.92), respectively] with

Table 4. Responsiveness of the symptoms, function and emotional and psychological well-being subdomains.

Subdomain	Stable ($n = 124$)		Remission to active disease ($n = 15$)		Active disease to remission ($n = 52$)	
	Mean (SD) change score	Effect size	Mean (SD) change score	Effect size	Mean (SD) change score	Effect size
Symptoms	0 (18)	0.02	41 (26)	2.05	−38 (22)	−1.79
Function	−1 (16)	−0.05	27 (22)	1.50	−38 (27)	−1.55
Emotional and psychological well-being	−1 (18)	−0.07	10 (22)	0.54	−15 (19)	−0.73

Table 5. Discriminatory power of the subdomains of the PMR-IS and the PMR-AS for detecting active disease.

Subdomain	AUC (95% CI)	*P*-value of AUC (*vs* PMR-AS)	Optimal cut-off value	Sensitivity, % (95% CI)	Specificity, % (95% CI)
Symptoms	0.89 (0.85, 0.94)	**0.03**	44.38	87 (77, 94)	81 (74, 86)
Function	0.86 (0.80, 0.92)	**0.002**	38.89	79 (67, 89)	85 (79, 90)
Emotional and psychological well-being	0.72 (0.64, 0.79)	**<0.001**	25.00	65 (52, 77)	67 (59, 73)
PMR-AS	0.94 (0.91, 0.97)	Reference	12.07	90 (80, 96)	86 (80, 91)

Significant values in bold.

an optimal cut-off point of 44.4 and 38.9, respectively (Table 5). The emotional and psychological well-being subdomain showed a moderate discriminative power for active disease with an AUC of 0.72 (95% CI 0.64, 0.79) and an optimal cut-off point of 25.0. However, the AUC of the PMR-AS was higher than the AUC of the subdomains of the PMR-IS [AUC 0.94 (95% CI 0.91, 0.97), optimal cut-off point 12.1, $P < 0.05$ for all subdomains; Table 5 and Fig. 1].

Discussion

In 2022, the first PMR-specific PROM was developed, called the PMR-IS [12]. Until now, this new PROM was only validated in a cross-sectional postal survey. To our knowledge, this study provides the first external validation of the PMR-IS in a prospective cohort study. In this study, we found that the symptoms, function and emotional and psychological well-being subdomains had good internal consistency and construct validity. In contrast, the glucocorticoid side effects subdomain had an insufficient internal consistency. In addition, only one-third of the prespecified hypotheses for construct validity were satisfied, suggesting that the PMR-IS does not adequately capture glucocorticoid side effects. However, glucocorticoid side effects are an important aspect in the follow-up of PMR patients [16–18]. Treatment modifications always need to be balanced between symptoms and treatment side effects, certainly since PMR itself does not cause irreversible damage. In addition, glucocorticoid myopathy can be difficult to distinguish from active disease, which may lead to an unnecessary delay in glucocorticoid tapering or to an increase in the glucocorticoid dose. In other words, a PROM that can adequately measure both symptoms and signs associated with active disease and glucocorticoid side effects may help to determine the optimal glucocorticoid tapering schedule and to identify patients who would benefit from early introduction of glucocorticoid-sparing agents.

Similar to the results of the original study [12], a floor effect was present in the function and the emotional and psychological well-being subdomains. This can cause problems with the interpretability and content validity [13, 19], but possibly the impact of PMR in patients with such low scores might be sufficiently low. As a result, adding more items for further differentiation might not be necessary or beneficial, as it would also increase the burden of completing the questionnaire.

In the original PMR-IS validation study, patients were asked to complete the questionnaire twice, once based on their current situation and once by thinking back to how they felt at the time of diagnosis [12]. This carries a high risk of recall bias and bias due to response shift. In addition, only a small number of patients worsened between diagnosis and the time of the study, with small mean change scores and high variability. Consequently, there was rather limited evidence on the PMR-IS's responsiveness. In this study, we showed that the scale had very good responsiveness with large effect sizes for the symptoms and function subdomains and medium effect sizes for the emotional and psychological well-being subdomain in case of a change in disease activity in both directions (remission to active disease and active disease to remission).

In addition, we found that the discriminatory capacity for active disease was good for the symptoms and function subdomains and moderate for the emotional and psychological well-being subdomain, which further confirms the good responsiveness. The PMR-AS performed significantly better than the subdomains of the PMR-IS. Of course, the PMR-AS was specifically developed as a disease activity measure. In contrast, the PMR-IS was developed to quantify the impact of PMR on patients suffering from this disease and should not have a perfect discriminatory capacity for active disease, so they are complementary to each other.

The major strength of this study is its prospective observational design with follow-up of the patients until 1 year after diagnosis. This study also has some limitations. First, patients were not systematically asked to refill the PMR-IS after a short period of time, precluding evaluation of test–retest reliability. However, the mean change scores and effect sizes between visits with stable disease were very low. Second,

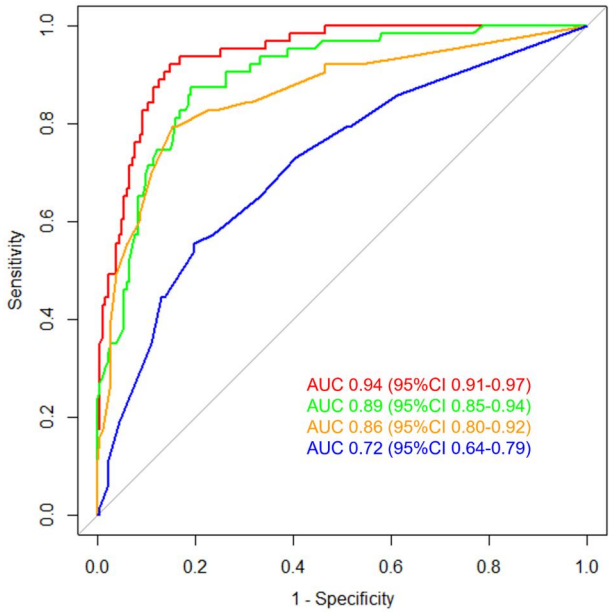

Figure 1. ROC curve for the symptoms (green), function (orange) and emotional and psychological well-being (blue) subdomains of the PMR-IS and the PMR-AS (red) for detecting active disease

patients were not asked how much they had changed between two visits. Therefore, the minimal important change could not be calculated. Third, all patients had a recent diagnosis, leaving uncertainty about whether the PMR-IS would perform similarly in a cohort with more established PMR. In addition, some data were missing, which was handled with multiple imputation. Finally, the forward and backward translation was performed by only one person.

In conclusion, we confirm that the symptoms, function and emotional and psychological well-being subdomains of the PMR-IS have good measurement properties, except for a floor effect in the function and emotional and psychological well-being subdomains. However, the glucocorticoid side effects subdomain did not show adequate internal consistency and construct validity, necessitating further validation and possibly improvement of the items prior to application in clinical trials and daily practice.

Supplementary material

Supplementary material is available at *Rheumatology Advances in Practice* online.

Data availability

All relevant data are reported in the article. Additional details can be provided by the corresponding author upon reasonable request.

Authors' contributions

L.M. was responsible for conceptualization, methodology, validation, investigation, formal analysis, writing the original draft, review & editing and visualization. M.D. and A.B. were responsible for conceptualization, methodology, formal analysis and review and editing. E.D.L. was responsible for investigation and review and editing. D.B. and S.V. were responsible for conceptualization, methodology, investigation, review and editing and supervision.

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