Feasibility and face validity of outcome measures for use in future studies of Polymyalgia Rheumatica (PMR): An OMERACT Study

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Objective

The aim of this study was to survey participants with PMR to evaluate the face validity, acceptability and domain match of proposed candidate outcome measures.

Methods

A structured, online, anonymous survey was disseminated by patient support groups via their networks and online forums. The candidate outcome measures comprised: 1. visual analogue scale (VAS), numerical rating score (NRS) to assess pain; 2. VAS, NRS and duration to assess stiffness; 3. the modified Health Assessment Questionnaire (mHAQ) and Health Assessment Questionnaire Disability Index (HAQ-DI) to assess physical function; 4. C-reactive protein (CRP), and erythrocyte sedimentation rate (ESR) to assess inflammation. Free text answers were analysed using descriptive thematic analysis to explore respondents' views of the candidate instruments.

Results

Seventy-eight people with PMR from six countries (UK, France, USA, Canada, Australia and New Zealand) participated in the survey. Most respondents agreed candidate instruments were acceptable or “good to go”.

Free text analysis identified five themes which participants felt were inadequately covered by the proposed instruments. These related to: (i) the variability, context and location of pain, (ii) the variability of stiffness, (iii) fatigue, (iv) disability, and (v) the correlation of inflammatory marker levels and severity of symptoms, sometimes reflecting disease activity and other times not.

Conclusion

Participants reported additional aspects of their experience which are not covered by the proposed instruments particularly for the experience of stiffness and impact of fatigue. New patient-reported outcome measures are required to increase the relevance of results from clinical trials to patients with PMR.

Key messages

- There was some support for use of existing pain and stiffness scales in PMR but patients identified limitations due to lack of specificity for their disease
- Patients with PMR identified that fatigue is an important part of their experience of living with PMR
- New patient-reported outcome measures are required to ensure that clinical studies capture outcomes that truly matter to patients.

Declaration of Helsinki

This study complies with the declaration of Helsinki. Ethical approval was obtained from the University of East Anglia research ethics committee (2017/18-81).

Conflict of interest

The authors declare no conflict of interest.

Funding

OMERACT (Outcome Measures in Rheumatology) is an independent initiative of international health professionals interested in outcome measures in rheumatology.

Introduction

Polymyalgia rheumatica (PMR) is a common inflammatory condition, common in older people, characterised by pain and stiffness in the muscle groups of the shoulder and pelvic girdle. Prevalence figures vary widely and point estimates are affected by study design and choice of classification criteria resulting in estimates of 0.1% in Portugal, 0.7% in the US and to 1.5% in the UK (1-4). Treatment with glucocorticoids (GCs) has been standard practice since the 1960s, but prescribed regimens lack standardisation, with wide variation in clinical practice (5, 6). One barrier to finding newer effective treatment is the lack of robust, validated and reliable outcome measures to capture disease activity and patient outcome (7). Different clinical response measures have been used in PMR but there is no consensus on their use clinically, particularly regarding morning stiffness duration which is considered too simplistic to capture the functional impact of stiffness from the patient perspective (8-10). In addition many of these measures have yet to be validated fully for PMR. The Outcome Measures in Rheumatology (OMERACT) PMR Working Group is assessing the evidence- base and usefulness of existing outcome tools to record disease activity in PMR, using the OMERACT filter contained within the OMERACT handbook (11-13).

The purpose of this study was to gain the views of patients with PMR and their views on the face validity, acceptability, feasibility, domain match and overall acceptability of the identified candidate instruments (14).

Patients and Methods:

Identification of candidate instruments

A Core Domain Set and candidate instruments were identified through Delphi rounds of clinicians and patient research partners with an interest in PMR, with the methods published previously (14). The identified core domains and instruments comprise: 1. Pain assessed by the visual analogue scale (VAS) and numerical rating score (NRS), 2. Stiffness assessed by the visual analogue scale (VAS), the numerical rating score (NRS) or duration of morning stiffness, 3. Physical Function assessed by the modified Health Assessment Questionnaire (mHAQ) and the Health Assessment Questionnaire Disability Index (HAQ-DI) and 4. Laboratory markers of inflammation assessed by C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR).

Design

This was an online survey with descriptive qualitative analysis of free-text responses.

Sampling frame

Google Docs links were created for each instrument and included in the Newswire newsletter of the charity PMRGCAuk, which is distributed to 1800 readers, and Web Links appeared on the HealthUnlocked forum which has 6986 members. Participants responding to the adverts completed the online questionnaires in keeping with a convenience sampling method.

Data collection

Four separate surveys – one relating to each core domain - were developed iteratively amongst members of the OMERACT PMR Working Group and hosted on the Web using Google Docs (see

http://www.pmrgca.co.uk/content/omeract for the relevant links). The questionnaires included both closed and free text questions. Each survey introduced the aims and purpose of the surveys, and the aims of OMERACT.

The online surveys went live on 24th April 2018 and closed on 3rd July 2018. Unique ID numbers and time stamps were generated at the time the surveys were completed by participants. All surveys were in English with respondents answering in English.

Data analysis and rigour

Participants were invited to answer each of the four surveys which i) asked for their assessment of the domain match and feasibility of each candidate instrument and ii) provided a free text section (with no word limit) to provide more in-depth feedback, particularly regarding missing items that were important to them in terms of their experience of PMR. Respondents recorded when they were diagnosed with PMR, what dose of GCs they were taking and whether they felt their PMR was active currently. Finally, respondents were asked to give a global overall assessment of each of the identified candidate instruments as either green (I approve), amber (some reservations) or red (not right / should not be used).

Inductive thematic analysis was used to analyse the free text responses. Individual participant responses were downloaded and the free text answers broken into operative phrases and grouped by theme. Themes were identified independently by two researchers (MY and KG), with review by the executive PMR Working Group which comprises clinicians and researchers with expertise in PMR, and patient partners.

Ethical considerations

This study complies with the declaration of Helsinki. Ethical approval was obtained from the University of East Anglia research ethics committee (2017/18-81). Completion of the survey assumed consent. No identifiable data were collected. All downloaded information was kept confidential and individual responses recorded numerically in order of chronological completion of the survey. MY was the custodian of the data.

Results:

A total of 78 participants with PMR completed at least one of the surveys and came from six countries (UK, France, USA, Canada, Australia and New Zealand) representing three continents (Europe, North America and Oceania). The disease duration ranged from new diagnosis to 17 years and doses of prednisolone ranged from 0 mg to 50 mg (nine had ceased glucocorticoid therapy). Participants also stated whether they thought their PMR was active, with 64% reporting active disease, 23% in remission (of whom 28% were no longer taking glucocorticoids) and 13% who were not sure.

There were 45 responses for the survey on pain and its measurement by VAS or NRS; 45 for stiffness as measured by either VAS, NRS or duration of morning stiffness; physical function assessed by HAQ-DI (n=78) or mHAQ (n=30); and 64 responses for the survey on laboratory markers of inflammation as captured by either CRP or ESR.

Most respondents agreed the candidate instruments had face validity and were feasible to complete: full approval (green, "good to go") for pain VAS was 66.7%, for pain NRS was 59.3%, for stiffness VAS was 51.9% and for stiffness NRS was 48.2%. The proportion with full approval for stiffness duration was 50%, for physical function was 68.5% for HAQ-DI, and 53.3% for mHAQ. 56.3% of respondents agreeing that CRP or ESR reflected disease activity in terms of levels of inflammation. The overall judgement of the candidate instruments and the participants' self-reported disease activity are shown in Table 1.

Respondents provided free text answers (proportion giving free text responses was 38% for the survey on pain, 53% for stiffness, 50% for HAQ-DI, 53% for MHAQ, and 66% for inflammatory markers), which allowed for more nuanced feedback on use of the instruments under test.

There were five themes identified, based on respondents' recollection of symptoms and their comments as to the usefulness of the candidate instruments. The themes related to: the variation, context and location of pain, the location and timing of stiffness, fatigue, inability to perform tasks that had been uninhibited prior to their diagnosis of PMR, and the variable correlation of inflammatory markers with severity of symptoms.

Pain

Overall, respondents thought both a VAS or NRS could capture pain, but gave suggestions on how this can be improved, with the expressed need to capture the variation in pain symptoms which occur throughout the day, and record the impact of activity upon its severity.

Theme 1 – Variation in pain, contextualisation and association to movement

"There is no opportunity here to indicate whether the pain suffered is constant, or intermittent; or, whether it is worse at different times of day, or even if it is affected by weather, or the seasons of the year. Or if particular activities exacerbate the pain." (#35)

"I may not have pain while sitting, may have a pain of 50 […mm on a VAS] *when turning over in bed and 75* […mm on a VAS] *when bending to pick up an object. There needs to be context. Possibly combine with the disability assessment activity items." (#36, #37))*

"Pain is variable at different times of the day and depends on what activities I try to do."(#24)

"Muscles more painful if sudden movement than slow. Hard to quantify." (#40)

Sub-theme 1 – Site of pain

Respondents noted that there was no chance to state the site of pain.

"It needs breaking down to localised pain, i.e. pain in shoulders, pain […in] *thighs, etc."(#12)*

Stiffness

Theme 2 – Location and timing of stiffness

Respondents commented on the lack of ability to describe where the stiffness affects them.

"Flexibility, strength, time e.g. after starting to walk till stiffness starts, time from stiffness e.g. on standing to being able to move again…how long after standing up are you able to walk?" (#52)

"Break down arms, legs, shoulders, neck."(#12)

"It does not ask the site of the stiffness." (#46)

"Time of day, therefore relevance to effect of stiffness."(#10)

Sub-theme 2 – Anchoring statements

With both the VAS and NRS, participants highlighted that anchoring statements might be helpful in quantification of stiffness.

"Perhaps an explanation as to what each number might mean in terms of stiffness e.g. 50 = a distracting stiffness affecting range of movement." (#2)

"Stiffness with specific activities would provide a clearer picture." (#37)

"Examples of stiffness levels." (#19)

Physical Health

The participants had several comments to make about the usefulness of HAQ-DI and mHAQ and its ability to record the impact of PMR on physical health; most participants highlighted the absence of questions concerning activities deemed difficult for patients with PMR. Another common theme amongst participants was that fatigue is a common symptom in PMR, which has a big impact on physical function, yet is not measured by either of these instruments.

Theme 3 – Fatigue

"Fatigue is a major factor with ability to complete activities and should be measured." (#7)

"Brain fog, lack of focus impaired judgement." (#34)

"There were no questions related to fatigue/tiredness as related to quality of life, or our inability to enjoy/take part in social events, or how we no longer "fit in," because our diminished mental capacity (memory, focus, etc) excludes us from many conversations." (#52)

Theme 4 – Impairment of function - Completion of tasks that previously were uninhibited

The activities were diverse and described many aspects of daily life. In particular, the tasks mentioned most frequently were driving an un-adapted car, shopping, cooking, getting dressed, hanging out washing, and the ability to carry out tasks related to personal hygiene. Although the HAQ-DI and mHAQ ask questions relating to activities of daily living, the following quotes reveal aspects that respondents think are missing.

"Cleaning teeth, picking up a pet or small child, making/washing bedclothes, applying cream or lotions, wiping yourself after going to the toilet." (#68)

"Can you prepare a hot cooked meal by yourself using a normal oven? Can you change the linen on your bed? Can you hang washing on a washing line to dry?" (#45)

"Are you able to get food in and out of your oven? Are you able to get food in and out of your refrigerator? Are you able to brush or dry your hair? Have you had to give up any forms of activity since developing your condition?" (#24)

"Has your PMR in the last week prevented you from completing any tasks, or activities you would normally be able to do? Have you had to take any or an increased amount of analgesia to be able to complete activities of daily living? (#4)

"Could include fastening a bra - this was impossible for me and is a marker - can do it when on [prednisolone] but not otherwise - but doesn't apply to men, clearly." (#74)

In the whole respondents preferred the HAQ-DI over the mHAQ, noting that a number of questions were missing from the mHAQ:

"Things such as reaching up for items and opening items requiring finer motor movements. (As in the first questionnaire [HAQDI] - which was much easier to complete too.)" (#28)

"Q9) Climb a flight of 10 (or X number) of stairs. Q10) Turn over in bed at night. Q11) Sit down on the toilet. Q12) Reach your arms vertically towards the ceiling/upwards." (#6)

"Housework tasks that involve bending down, kneeling down, or sitting on the floor cause problems. I can struggle down, but getting up needs furniture or another form of support. PMR affects specific muscle groups e.g. shoulders, hips, knees - should the questions posed relate more specifically to activities involving these muscle groups?" (#19)

Inflammation

With respect to measurement of CRP or ESR, respondents commented that while they were useful for measuring inflammation levels, their doctor did not always monitor them, and that symptoms were a more important indication. Indeed, several participants stated that their inflammation markers did not seem to reflect their symptom flares.

Theme 5 - Symptoms and variable correlation to inflammatory marker readings

"Mine were never raised so had hard time diagnosing…using them for me is not a good result." (#50)

"At the beginning of my illness there was a distinct correlation between ESR rate and my PMR - but recently sometimes I have a lowish reading but my symptoms are severe, and sometimes a higher reading and I don't have severe symptoms." (#58)

"Need to be looked at together with symptoms as lots of things [can] cause raised markers." (#47)

While other participants found that measuring the CRP and or ESR was useful in establishing a diagnosis:

"They let me know that the steroids I was prescribed after I was first diagnosed and 3 months later had effectively reduced the level of inflammation, which corroborated with the reduction in my symptoms. This was reassuring." (#15)

Discussion

This study explored the face validity and feasibility of candidate instruments for use in future studies enrolling individuals with PMR. From participants' free text responses, descriptive inductive thematic analysis was used to assess those aspects of their lived experience of PMR which they felt were not covered by the current candidate instruments. The findings show that the majority of survey respondents agree that the identified candidate instruments were acceptable in terms of their face validity and feasibility. The responses were particularly helpful in determining which items relevant to the core domains of pain, stiffness, physical health and inflammation were missing, or could be better captured than with the identified candidate instruments.

Five themes emerged from the descriptive thematic analysis: the variation, context and location of pain, the location and timing of stiffness, fatigue, inability to perform tasks which had been uninhibited prior to PMR onset, and the variable correlation of inflammatory markers to severity of symptoms. Opinions varied about the importance of inflammatory markers, with divergent views being expressed on the topic. This appeared to be more of a challenge to the inclusion of the domain itself, rather than a preference for one instrument over another. This same issue had occurred previously during the core domain set development work. However, both physicians and patients felt inflammatory markers were the best measure of pathophysiology, but mentioned caveats in interpreting results at the individual patient level. It is a limitation of our methodology that we were unable to explore this topic in more depth with the participants. It is important to note the differences between clinician-derived versus patient-reported outcome measures (PROMs), with the former trying to capture objective pathological change of disease, and the latter the impact on quality of life. Both viewpoints should be taken into consideration.

There are advantages in using a well-established PROM such as the HAQ-DI, which has been evaluated in many rheumatic diseases but has many items which will not be specific to PMR. A disease-specific PROM may result in higher face validity for patients: feedback from this survey supports this, with requests for more detailed questionnaire items. There is possibly a role for both. However, no fully-validated disease-specific PROM for PMR currently exists.

Amongst our survey responders, feedback about stiffness was particularly common amongst those who had active disease, with 39.4% identifying some concerns with the use of stiffness duration, compared to 27.3% for a VAS to record stiffness severity. The questions regarding stiffness for this survey simply asked respondents' views as to whether a VAS or NRS allowed them to communicate their severity of stiffness. There were no lead-in questions such "over the past week" or "within the last 24 hours". It is possible that without a temporal frame to the questions, respondents felt unguided, leading to a higher proportion stating they had concerns. However, the free text responses suggest that patients would prefer to report stiffness in terms of functional impairment or limitation (9).

A qualitative study which explored the impact of PMR on patients' lives was carried out in the UK amongst 20 patients from South Yorkshire (15). There were five themes identified: pain, stiffness

and weakness, disability treatment and disease course, experience of care and psychological impact. The same research team is now developing a PROM for PMR, and carried out a postal questionnaire of 28 patients with PMR from the community and hospital setting, to test the face validity of a "long-form" of the proposed PROM, assessed with a second questionnaire called QQ10 (16). The research found similar concerns to the current study regarding the definition of stiffness, with participants stating that duration of stiffness as a measure failed to adequately reflect the impact of this symptom on their lives (16).

From the free text responses and resultant thematic analysis, it is clear that the experience of stiffness is complex and has contextual factors. It may be to the benefit of the medical community that a PROM is developed to better capture and measure this important symptom for patients with PMR.

Regarding pain and stiffness captured by a VAS or NRS, the participants tended to modify or improve statements, such as including location of the symptom and anchoring statements. To capture physical function, participants preferred the HAQ-DI to the shorter mHAQ. However, fatigue was often cited and is missing from both the HAQ-DI and mHAQ. Fatigue is not just important to patients with PMR: qualitative research, replicated internationally, shows that patients with Rheumatoid Arthritis (RA) experience fatigue as uncontrollable and overwhelming, yet find it largely ignored by clinicians (17). Currently, fatigue is included as an "important" rather than "core" domain for patients with PMR within the proposed OMERACT domain set, mostly due to lack of consensus between clinicians and patients as to whether it represents a fundamental feature of PMR. However, the results from this survey underline its importance for patients and the need for further research. Assessing properties of the candidate instruments is an aim of future work by the OMERACT group and it is interesting to see the composite score, RAPID3 which combines a VAS for pain, score of physical function and VAS of patient global assessment was more sensitive to change than ESR or duration of morning stiffness (18). However evaluating composite outcomes, which cross multiple domains of the Core Domain Set, was outside the scope of this study.

The strengths of the current study are its size and the different nationalities of respondents; however there are limitations. Since this was an online survey with participants self-completing the questionnaires, this may have resulted in a less than representative sample. For example, more actively motivated and possibly more affluent people might choose, and have the resources to complete the online surveys. We did not ask for the age of participants so were unable to draw any conclusions as to how this might affect the results of the survey or to be able to generalise whether our respondents are typical for a cohort of PMR patients. In addition, diagnoses could not be validated by applying classification sets designed to select homogeneous groups of patients to recruit to research studies: the reason for this was to survey as heterogeneous a sample as possible in order to capture the widest expression of views. The drawback of this approach is that it cannot be ascertained whether some of the symptoms described are attributable to a cause other than PMR. In addition, we cannot say which single outcome measure patients preferred over the others as identifying a "top" instrument was not the objective of this study as the Core Domain Set had already been set. Our research question was how individual instruments matched to each domain. Finally, the survey was in English, which may have limited responses from non-English speakers.

The conclusion of this work is that the domain match and feasibility of the proposed candidate instruments for each of the identified core domains are on the whole acceptable to patients with PMR. However, there is concern that several items of particular importance to patients, for example fatigue, remain missing from these outcome measures and suggests that fatigue should move from "important" to a "core" domain within OMERACT. Furthermore, participants consistently indicated that duration of stiffness, as an instrument, failed to reflect their real-life experience of this symptom. These may both reflect a disconnect between traditional medical teaching about the manifestations of PMR and what it is like for patients who experience the disease. Ultimately, outcome measures which reliably capture disease extent and severity in clinical trials will be vital for the success of future novel therapeutic options in PMR.

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Table 1. Participant's global assessment of the proposed candidate instruments

	Approve (%)			Some reservations (%)			Not right (%)		
Pain	VAS	NRS		VAS	NRS		VAS	NRS	
Active (n=33)	63.6	57.6		24.2	27.3		12.1	15.2	
Remission (n=7)	100	100		0	0		0	0	
Not sure (n=5)	60	46.7		40	53.3		0	0	
Total (n=45)	66.7	59.3		25.9	31.5		7.4	9.3	
Stiffness	VAS	NRS	Dur	VAS	NRS	Dur	VAS	NRS	Dur
Active (n=33)	63.6	57.6	57.6	27.3	33.3	39.4	9.1	9.1	3
Remission (n=7)	46.7	46.7	53.3	46.7	46.7	40	6.7	6.7	6.7
Not sure (n=5)	100	100	83.3	0	0	16.7	0	0	0
Total (n=45)	51.9	48.2	50	29.6	33.3	37	7.4	7.4	1.9
Physical Function	mHAQ	HAQ-DI		MHAQ	HAQDI		MHAQ	HAQDI	
Active* (n=50)	52.6	73.9		47.4	26.1		0	0	
Remission* (n=18)	57.1	58.8		42.9	41.2		0	0	
Not sure* (n=10)	50	60		25	40		25	0	
Total* (n=78)	53.3	68.5		43.3	31.5		3.3	0	
Inflammation	CRP or ESR			CRP or ESR			CRP or ESR		
Active (n=43)	60.5			34.9			4.7		
Remission (n=13)	46.2			53.8			0		
Not sure (n=8)	50			50			0		
Total (n=64)	56.3			40.6			3.1		

VAS – visual analogue scale, NRS – numerical rating scale, Dur – stiffness duration, mHAQ – modified health assessment questionnaire, HAQ-DI – health assessment questionnaire disability index, CRP – c-reactive protein, ESR – erythrocyte sedimentation rate. *numbers reported are for the survey on HAQ-DI, there were 30 responses for the MHAQ survey of whom 19 respondents said their PMR was active, 7 in remission and 4 not sure.