Advancing the Development of Patient-reported Outcomes for Adult Myositis at OMERACT 2016: An International Delphi Study

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ABSTRACT. ***Objective.*** To define a set of core patient-reported domains and respective instruments for use in idiopathic inflammatory myopathies (IIM). Previously, we reported a systematic literature review on patient-reported outcomes (PRO) in IIM followed by conducting international focus groups to elicit patient perspectives of myositis symptoms and effects.

Methods. Based on qualitative content analysis of focus groups, an initial list of 26 candidate domains was constructed. We subsequently conducted an international modified Delphi survey to identify the importance of each of the 26 domains. Participants were asked to rate each domain on a scale of 0–10 (0 = not important, 10 = very important).

Results. In this first round of the Delphi survey, 643 patients participated from the United States (n = 543), Sweden (n = 49), and South Korea (n = 51). Of the 26 domains, 19 (73%) were rated of high importance (≥ 7/10). The top 5 domains were muscle symptoms, fatigue, interactions with healthcare, medication side effects, and pain. During Outcome Measures in Rheumatology (OMERACT) 2016, we discussed the goal for ultimate reduction in the number of domains and the importance of considering representation of healthcare providers from other specialties, caregivers, representatives of pharmaceutical industries, and regulatory authorities in the next rounds of Delphi to represent broader perspectives on IIM.

Conclusion. Further prioritization and a reduction in the number of domains will be needed for the next Delphi. At the next biennial OMERACT meeting, we aim to present and seek voting on a Myositis Preliminary PRO Core Set to enable ultimate measure selection and development. (First Release August 1 2017; J Rheumatol 2017;44:1683–7; doi:10.3899/jrheum.161252)

Key Indexing Terms:
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Idiopathic inflammatory myopathies (IIM) affect muscle and extramuscular organs, resulting in significant limitation in activities of daily living and health-related quality of life[1,2,3,4]. However, outcome measures used in clinical studies for IIM are often based on the measurement of pathophysiologic manifestations of the disease such as muscle weakness, elevated muscle enzymes, and skin changes, whereas the patients' perceptions of life effect of the disease has not been systematically addressed in clinical studies or routine clinical practice[3].

The Outcome Measures in Rheumatology (OMERACT) Myositis Special Interest Group (SIG) was established to define a set of core domains and ultimately identify instruments that reflect the symptoms and life effects that are experienced by people living with myositis. A core set is defined as the minimum number of domains needed to describe outcomes in clinical trials or clinical practice. A domain according to OMERACT is a further specification of an aspect of health, for example pain or physical function[5,6]. The Myositis SIG consists of patient research partners (PRP) with myositis, healthcare providers, and quantitative and qualitative methodologists who are interested in IIM.

At the OMERACT meeting in 2012, the newly formed Myositis SIG presented a systematic literature review on patient-reported outcome measures (PROM) used in the IIM[7]. None of the extant measures had been developed following the currently recommended qualitative methodology outlined by OMERACT and other groups for domain identification and prioritization[8,9,10,11].

To study patients' experiences of disease, we previously reported the results of several focus group sessions conducted in 3 countries, and analyzed transcripts to identify domains that were described by patients as relevant to their experience of myositis[12]. These results were presented at the OMERACT meeting in 2014. At OMERACT 2016, the Myositis SIG presented the results from the first round of an international Delphi exercise to prioritize domains.

MATERIALS AND METHODS

Identifying domains important to patients to assess. Based on the qualitative content analysis of transcripts from the 11 focus groups involving 66 participants from 3 countries, an initial list of 26 candidate domains was constructed[12,13]. During discussions between SIG investigators and PRP, content and wording of the items for the first round online modified Delphi were revised until they best reflected the original intended domains and subdomains and would be comprehensible by patients. The survey was further translated into Korean and Swedish, and discussed with PRP within these countries to provide additional assurance of content comprehension and meaning.

Delphi survey. Patients with adult PM and DM in the United States, Sweden, and South Korea were invited to participate in the first Delphi using an Internet-based survey platform (www.qualtrics.com). Participants were asked to rate each domain on a scale of 0–10 (0 = not important, 10 = very important). Participants were then asked to add any additional domain(s) of importance in a free text box. Additional domains added by patients were discussed among SIG members for inclusion in future Delphi surveys. This study was approved by the International Review Board of Johns Hopkins University Hospital (IRB NA_ 00098790).

Statistical analyses. Mean scores were calculated for individual items. *A priori*, we had defined domain importance according to categories for analysis (< 4 low importance, ≥ 4 and < 7 moderate importance, and ≥ 7 high importance). ANOVA was used to compare the response of the domains between the 3 countries.

RESULTS

The OMERACT 2016 SIG session. The purpose of the session was to review previous research, present current Delphi results, and develop a research agenda. Two PRP, 1 OMERACT Fellow, and 5 healthcare providers (3 physicians, a physical therapist, and an occupational therapist) representing 5 countries and 3 continents led the Myositis SIG session. To set our focus on the patients' perspective in myositis, 2 PRP (CS and IdG) shared their experiences of living with DM and PM.

First-round online Delphi survey for patients with adult PM and DM. There were 826 patients from the United States (n = 551), Sweden (n = 220), and South Korea (n = 55) who were invited to participate, and 643 (77.8%) patients from the United States (n = 543), Sweden (n = 49), and South Korea (n = 51) completed the Delphi exercise. The mean (SD) age was 54.5 (13.3) years with disease duration of 8.1 (7.8) years, and 81% were women. Of 643 patients, 353 (54.9%) had DM (Table 1).

Of the 26 domains, 19 (73.1%) were rated very important (i.e., score ≥ 7/10; Table 2). The top 5 rated domains were muscle symptoms, fatigue, interaction with healthcare and authorities, medication side effects, and pain. None of the domains were rated by patients as having low importance (i.e., score < 4). Except for "effect on household activity" and "interaction with healthcare and authorities," the rating of each domain did not differ among patients from 3 countries. Interestingly, patients with PM rated "skin involvement" of higher importance than patients with DM (7.9 ± 2.4 vs 5.5 ± 3.4; $p < 0.001$; Appendix 1). Suggestions in the free text box were provided by patients; however, after review by SIG members it was concluded that no additional domain information would be added by their inclusion.

Domain selection for the next Delphi survey. Based on discussions at OMERACT 2016 and subsequent phone and video teleconferences among SIG members, it was recognized that some domains represented overlapping constructs and could be potentially merged to reduce the total number of domains brought forward into the next round. For example, the domains "exercise" and "physical activity" could be grouped into 1 domain called "physical activity." In addition, after discussion reviewing the work of the OMERACT Contextual Factors SIG and the International Classification of Functioning, Disability and Health nomenclature, the domain "social support" was recognized to be more appropriately considered as an environmental or contextual factor, and would thus be excluded from the next

Table 1. Baseline characteristics of 643 patients with myositis who completed Delphi survey. P values were generated by ANOVA.

Characteristic	USA, n = 543	Sweden, n = 49	South Korea, n = 51	Total, n = 643	p
Age, yrs, mean ± SD	54.2 ± 13.0	62.6 ± 11.8	49.7 ± 14.1	54.5 ± 13.3	0.001
Female, n (%)	446 (82.1)	36 (73.5)	40 (78.4)	522 (81.2)	0.289
DM, n (%)	283 (52.1)	26 (53.1)	44 (86.3)	353 (54.9)	< 0.001
Disease duration, yrs, mean ± SD	7.9 ± 7.3	10.1 ± 10.1	7.8 ± 7.3	8.1 ± 7.8	0.170

DM: dermatomyositis.

Table 2. Importance rating of 26 candidate domains included in the first round of Delphi survey. Values are mean ± SD.

Domain: "On a scale of 0–10, how important…"	USA, n = 543	Sweden, n = 49	S. Korea, n = 51	Total, n = 643
1. Is muscle symptom to you (weakness, low endurance)?	9.2 ± 1.6	9.0 ± 1.2	8.7 ± 1.8	9.1 ± 1.6
2. Are joint symptoms to you (for example: stiffness, swelling, pain in joints or muscle tendons)?	7.4 ± 2.8	7.3 ± 2.8	8.0 ± 2.5	7.4 ± 2.8
3. Are skin symptoms such as rash, losing hair, and nail to you?	6.6 ± 3.2	6.0 ± 3.5	7.1 ± 3.2	6.6 ± 3.2
4. Is pain to you (for example: muscle pain)?	7.8 ± 2.7	7.5 ± 2.9	8.1 ± 2.2	7.8 ± 2.7
5. Is lung involvement to you (cough, shortness of breath)?	7.3 ± 3.2	7.4 ± 3.6	8.1 ± 2.7	7.3 ± 3.2
6. Are cardiovascular symptoms to you?	6.8 ± 3.3	7.4 ± 3.6	7.3 ± 3.0	6.9 ± 3.3
7. Is dysphagia to you (difficulty swallowing)?	6.9 ± 3.2	7.2 ± 3.3	6.8 ± 3.4	6.9 ± 3.2
8. Are gastrointestinal tract symptoms to you (constipation, upset stomach, diarrhea)?	6.5 ± 3.0	6.8 ± 3.1	6.6 ± 3.0	6.6 ± 3.0
9. Are dryness of eyes and/or mouth to you?	6.0 ± 3.0	6.4 ± 3.2	6.7 ± 3.1	6.1 ± 3.0
10. Is incontinence to you?	5.6 ± 3.4	5.6 ± 4.1	5.9 ± 3.1	5.7 ± 3.5
11. Are increased risk of infections to you?	7.5 ± 2.7	7.5 ± 3.1	7.6 ± 2.7	7.5 ± 2.7
12. Are medication side effects to you?	8.0 ± 2.3	8.2 ± 2.8	8.6 ± 1.7	8.0 ± 2.3
13. Is difficulty sleeping to you?	7.3 ± 2.7	7.4 ± 2.5	7.3 ± 2.9	7.3 ± 2.7
14. Is fatigue to you?	8.6 ± 1.9	8.3 ± 2.4	8.1 ± 1.9	8.5 ± 1.9
15. Is cognitive effect to you (such as memory, concentration)?	7.6 ± 2.7	7.4 ± 3.0	7.3 ± 3.2	7.6 ± 2.8
16. Is the effect on activities of personal care in everyday life to you?	7.6 ± 2.7	7.1 ± 3.3	7.3 ± 2.4	7.5 ± 2.7
17. Is the effect on household activities in everyday life to you?*	7.8 ± 2.3	6.8 ± 3.0	7.6 ± 2.1	7.7 ± 2.3
18. Is the effect on leisure activities in everyday life to you?	7.8 ± 2.2	7.7 ± 2.5	7.6 ± 2.0	7.8 ± 2.2
19. Is effect on work ability to you?	7.7 ± 2.8	7.4 ± 3.2	8.4 ± 1.7	7.7 ± 2.8
20. Is effect on social gatherings/activities to you?	7.2 ± 2.5	7.2 ± 2.9	7.7 ± 1.9	7.2 ± 2.5
21. Is effect on relation and/or intimacy to you?	7.1 ± 2.8	7.4 ± 2.7	7.2 ± 2.6	7.1 ± 2.8
22. Is emotional distress to you (for example: anxiety, depression, stress, and grief)?	7.4 ± 2.6	7.4 ± 2.9	7.8 ± 2.2	7.4 ± 2.6
23. Is it to assess how much you exercise?	7.5 ± 2.2	7.2 ± 2.8	8.0 ± 1.8	7.5 ± 2.3
24. Is it to assess how physically active you are?	7.7 ± 2.1	7.5 ± 2.6	7.9 ± 1.9	7.7 ± 2.1
25. Is it to assess your social support?	7.0 ± 2.4	6.8 ± 2.5	6.9 ± 2.2	7.0 ± 2.4
26. Is it to assess how interaction with healthcare and authorities works?*	8.1 ± 2.1	8.7 ± 2.2	9.0 ± 1.5	8.3 ± 2.1

*Importance ratings differed significantly among 3 groups ($p < 0.05$ by ANOVA).

Delphi round. Based on these decisions, a potential reduction to 24 domains could be used for the next round of the Delphi survey (Table 3).

A priori, it was originally intended that those domains classified as high importance would be included in a second Delphi round. However, in response to over 70% of the domains being classified as highly important, it was decided to reframe how we asked patients to evaluate these domains for the next Delphi. Attendees at the SIG meeting discussed other methods that may be useful. These included suggestions to rank order domains from 1 through 20. Ultimately, it was agreed upon to have each patient select the top 10 domains from among the list, then subsequently prioritize their top 5 in rank order. After the second round of Delphi survey, the top-ranked domains will be checked for their redundancy using a factor analysis. The ultimate goal is to identify a parsimonious group of domains to be measured as outcomes that adequately reflect the construct of interest; in this case, the life effect of myositis from the patient perspective.

DISCUSSION

At OMERACT 2016, the Myositis SIG presented the results of the first Delphi for domain prioritization, with the goal of

Table 3. Candidate domains for the following round of Delphi survey.

Candidate Domains
1. Muscle symptom (excluding pain)
2. Joint symptoms (excluding pain)
3. Skin symptoms (excluding pain)
4. Pain
5. Lung symptoms
6. Cardiovascular symptoms
7. Dysphagia (difficulty swallowing)
8. Gastrointestinal tract symptoms
9. Dryness of eyes and/or mouth
10. Incontinence
11. Increased risk of infection
12. Medication side effects
13. Difficulty sleeping
14. Fatigue
15. Cognitive effect
16. Personal care
17. Household activities
18. Leisure activities
19. Work ability
20. Social gathering
21. Relation and/or intimacy
22. Emotional distress
23. Levels of physical activity
24. Interaction with healthcare personnel and authorities*

*Authorities may encompass insurance companies, employers, regulatory agencies, etc.

defining a core set of PROM domains and instruments for inclusion in clinical trials of myositis.

Our study is notable for the participation of 643 patients from 3 continents in a Delphi exercise, with its content informed by antecedent international focus groups. In the first round of Delphi, participants rated 19 (73.1%) of 26 domains as highly important, indicating the broad range of symptoms commonly experienced by people with myositis. Despite the difference in cultural background among participants, ratings of domains differed in only 2 of the 26 domains ("effect on household activity" and "interaction with healthcare and authorities"), suggesting that patients with myositis from 3 different continents share similar experiences of the disease.

During the SIG session, wider engagement was suggested, including healthcare providers from other specialties, caregivers, representatives of pharmaceutical industries, and regulatory authorities. Their inclusion may help identify potential domains for clinical trials, but may not be necessarily prioritized by patients. Based on these recommendations, the next round of the Delphi exercise will include healthcare providers, caregivers, representatives from pharmaceutical industry and regulatory authorities, and patients from other countries and continents (e.g., Australia, South America, the Netherlands). However, it will be important to provide descriptors of domains for different audiences with exemplars as has been reported by other groups[14].

Achieving this research agenda will position us to present and seek voting on a Myositis Preliminary Patient Core Domain Set. This will enable our work to move forward in moving from domain selection to instrument identification and/or development using OMERACT Filters 1.0 and 2.0.

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APPENDIX 1. Comparisons of importance rating of 26 domains between patients with DM and PM. P values were generated by Student t tests. Values are mean ± SD unless otherwise specified.

Characteristics	DM, n = 353	PM, n = 290	p
Age, yrs	55.3 ± 14.0	53.4 ± 12.3	0.063
Female, n (%)	288 (81.6)	234 (80.7)	0.772
Disease duration, yrs	8.9 ± 7.9	7.1 ± 7.7	**0.004**
Domain: "On a scale of 0–10, how important…"			
1. Is muscle symptom to you (weakness, low endurance)?	9.2 ± 1.4	9.0 ± 1.7	0.188
2. Are joint symptoms to you (for example: stiffness, swelling, pain in joints or muscle tendons)?	7.4 ± 2.8	7.5 ± 2.7	0.752
3. Are skin symptoms such as rash, losing hair, and nail to you?	5.5 ± 3.4	7.9 ± 2.4	**< 0.001**
4. Is pain to you (for example: muscle pain)?	7.7 ± 2.7	8.0 ± 2.6	0.248
5. Is lung involvement to you (cough, shortness of breath)?	7.5 ± 3.2	7.2 ± 3.2	0.204
6. Are cardiovascular symptoms to you?	6.9 ± 3.2	7.8 ± 3.3	0.470
7. Is dysphagia to you (difficulty swallowing)?	6.9 ± 3.2	6.9 ± 3.3	0.978
8. Are gastrointestinal tract symptoms to you (constipation, upset stomach, diarrhea)?	6.7 ± 2.9	6.5 ± 3.0	0.439
9. Are dryness of eyes and/or mouth to you?	6.0 ± 3.0	6.1 ± 3.0	0.661
10. Is incontinence to you?	5.7 ± 3.4	5.6 ± 3.5	0.546
11. Are increased risk of infections to you?	7.6 ± 2.8	7.5 ± 2.7	0.510
12. Are medication side effects to you?	8.1 ± 2.3	8.0 ± 2.2	0610
13. Is difficulty sleeping to you?	7.3 ± 2.7	7.3 ± 2.6	0.869
14. Is fatigue to you?	8.6 ± 1.8	8.5 ± 2.0	0.458
15. Is cognitive effect to you (such as memory, concentration)?	7.4 ± 3.0	7.8 ± 2.5	**0.037**
16. Is the effect on activities of personal care in everyday life to you?	7.7 ± 2.6	7.2 ± 2.8	**0.021**
17. Is the effect on household activities in everyday life to you?	7.9 ± 2.2	7.4 ± 2.5	**0.019**
18. Is the effect on leisure activities in everyday life to you?	8.1 ± 1.9	7.5 ± 2.4	**0.002**
19. Is effect on work ability to you?	7.8 ± 2.8	7.7 ± 2.7	0.690
20. Is effect on social gatherings/activities to you?	7.5 ± 2.3	7.7 ± 2.7	**< 0.001**
21. Is effect on relation and/or intimacy to you?	7.3 ± 2.6	7.0 ± 3.0	0.214
22. Is emotional distress to you (for example: anxiety, depression, stress and grief)?	7.5 ± 2.6	7.3 ± 2.6	0.257
23. Is it to assess how much you exercise?	7.5 ± 2.6	7.3 ± 2.6	0.947
24. Is it to assess how physically active you are?	7.8 ± 2.0	7.5 ± 2.3	0.583
25. Is it to assess your social support?	7.1 ± 2.3	6.9 ± 2.5	0.217
26. Is it to assess how interaction with healthcare and authorities works?	8.5 ± 2.0	8.0 ± 2.2	**0.004**

Significant data are in bold face. DM: dermatomyositis; PM: polymyositis.

Correction

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