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Review of the Psoriatic Arthritis Working Group at OMERACT 12: A Report from the GRAPPA 2014 Annual Meeting

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Abstract (170 words)

At the 2014 annual meeting of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA), the psoriatic arthritis (PsA) working group of OMERACT (Outcome Measures in Rheumatology) presented a review of the progress made at the 2014 OMERACT meeting. Members of the PsA OMERACT working group presented work from the Patient Involvement in Outcome Measures for PsA initiative to improve the incorporation of patient research partners in PsA outcomes research, the results of discussions within the OMERACT breakout groups, and finally the voting results. The OMERACT 2014 participants had endorsed the need to update the PsA core set according to the Filter 2.0 framework. The breakout group discussions identified potential opportunities for revising the core set, including consolidating existing redundancy within the core set, improving incorporation of the patient perspective, and including disease impacts such as fatigue as a core criterion. GRAPPA members of the OMERACT working group now have a program of research to update the core set with the goal of seeking endorsement at OMERACT 2016.

Introduction

In 2006, at the eighth meeting of Outcome Measures in Rheumatology (OMERACT 8), members endorsed the psoriatic arthritis (PsA) core set of outcome measures to be used in randomized controlled trials (RCTs) and longitudinal observational studies.(1) Considerable work within the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) has been undertaken over the last eight years to develop appropriate individual and composite responder indices to capture disease activity.(2, 3) At the OMERACT 10 meeting in 2012, it became clear that much of the work of outcome measure development and domain selection had been undertaken with little or no incorporation of the patient perspective. The role of patients in outcome research is embedded at the heart of the OMERACT process,(4, 5) and has been accomplished through meaningful, ongoing inclusion of patient research partners (PRPs) In rheumatoid arthritis (RA), the acknowledged benefits of patient involvement have included the improved determination of the minimum clinically important differences (MCID) in patient-reported outcomes, development of definitions of remission and flare, and inclusion of fatigue and participation to the RA core set.(6, 7)

A number of initiatives on both sides of the Atlantic are underway to firmly embed the patient perspective in wider health research. The United States Congress has established the Patient Centered Outcomes Research Institute, the National Institute of Health Research in the United Kingdom has convened the INVOLVE group to promote patient involvement in the National Health Service, and the European League Against Rheumatism has published recommendations for the inclusion of the patient perspective in research.(8)

At the 2014 GRAPPA annual meeting, the PsA OMERACT working group presented a summary of the work of the Patient Involvement in Outcome Measures for Psoriatic Arthritis (PIOMPSA) group over the last two years. Results were also presented of the breakout group discussions and attendee voting at OMERACT 12, as well as a potential roadmap toward endorsement of a revised PsA core set at OMERACT 13 in 2016.

Presentations

The OMERACT 12 Psoriatic Arthritis working group overview

Dr. Niti Goel introduced the PsA OMERACT working group comprising two fellows, four co-chairs, three PRPs, one member of the OMERACT executive committee for liaison, and two additional GRAPPA member attendees (see Acknowledgments). The OMERACT PsA workshop consisted of presentations of the work undertaken since OMERACT 10 including the PIOMPSA initiative,(9) the Psoriatic Arthritis Impact of Disease (PsAID) study,(10) and the progress made towards development of composite disease activity measures.(2) Presentations at OMERACT were followed by breakout group discussions on the need to update the PsA core set and what revisions should be considered. Results from breakout groups were presented at a plenary session, followed by voting.(11)

Review of the patient involvement initiative (PIOMPSA)

The PIOMPSA effort was initiated in 2012 to improve incorporation of the patient perspective in PsA outcomes research within GRAPPA. The first meeting in Dublin, Ireland included equal numbers of rheumatologists and PRPs, and efforts have been made to preserve this balance to give PRPs an equal voice at the proceedings.(9) The PIOMPSA group discussed the relative lack of patient input in the development of the PsA core set and outcome measure development. They also undertook a systematic literature review to define current levels of patient involvement together with developing a roadmap to enhance integration of patient perspectives in future PsA research. The group identified the need to revise the existing PsA core set, primarily to ensure incorporation of patient involvement in domain selection and prioritization, but additionally to integrate the considerable research progress from 2006 onward, including;

- The 68/66 (tender/swollen) joint count has been identified as the optimal joint count for PsA assessment in clinical trials.(12)
- Tools to assess fatigue, enthesitis, dactylitis, and the measurement of axial disease have been developed and tested.(13-15)
- The Psoriasis Activity and Severity Index has been shown to be reliable when performed by rheumatologists or dermatologists.(16)

Updating the core set in light of these research findings would facilitate patient representation. It would also allow an opportunity for movement or incorporation of domains important to patients such as fatigue, dactylitis, and participation (work/leisure activities) that were not previously included.(9, 17) Dr. Goel acknowledged that the PRP role within GRAPPA needed to be formalized through the work done in the Building Bridges initiative.(18)

Update of the PsA core set, breakout group discussion and voting

Dr. William Tillett reviewed the results of the 2014 OMERACT 12 breakout discussions and voting. The existing PsA core set, endorsed at OMERACT 8 in 2006, was reviewed (**Figure 1**)(1) and compared with the new OMERACT Filter 2.0.(19) The new structure encourages researchers to consider domains within four core areas: pathophysiological manifestations, life impact, resource use, and death (**Figure 2**).(19) Domains are then placed within concentric spheres by decreasing importance and/or availability of applicable instruments and finally for the research agenda. The core (central) sphere should contain at least one domain from each of the four core areas. The middle sphere could contain several additional domains that may not be applicable for the central sphere but could be useful dependent on the individual study question. The final outer sphere could be reserved for additional domains of interest in the research agenda. Participants at the OMERACT workshop breakout groups were given a copy of the existing PsA core set and asked to consider the need for its revision and if so what changes to consider.

Feedback from the breakout groups identified a number of themes. There was general agreement on the need to revise the PsA core set, which would present opportunities to improve the existing set. An opportunity to amend existing redundancy within the core area of pathophysiology was discussed. An umbrella term such as inflammatory musculoskeletal disease for arthritis, enthesitis, dactylitis, and axial disease could be considered. Psoriasis activity may be considered as an encompassing term for skin and nail disease, and biomarkers for acute phase reactants. Life impact concepts emerging from the breakout discussions included a strong message to retain pain, health-related quality of life, physical function, and patient global in the core set, while adding fatigue, which attendees noted had also been ranked highly in the PsAID study.(10) Debate followed regarding the potential overlap of domains captured in the patient global measure as well as fatigue, with recognition of the increasing evidence that it is legitimate to move items like dactylitis,(20) fatigue,(21) and enthesitis(22)

from former positions in the second circle to higher prioritization in the inner circle, especially as tools had been developed and tested since the initial core set was created.

The proposal to revise the PsA core set was endorsed with a 100% vote by the OMERACT workshop participants—notably the first time a unanimous vote had been achieved within OMERACT. The PsA core set will therefore be the first to undergo revision using the OMERACT Filter 2.0. Consensus was also achieved on retaining the patient global within the core set (endorsed with 70% vote) as well as adding fatigue (endorsed with 72% vote).

Conclusion

At the 2014 OMERACT 12 PsA workshop there was unanimous endorsement for the need to update the PsA core set. The results of the OMERACT breakout group discussions highlighted opportunities to involve patients as well as add, move, or merge existing domains to improve existing redundancy. Over the next two years, GRAPPA working group members will focus on revising the PsA core set according to the OMERACT Filter 2.0, with the goal of seeking endorsement at OMERACT 13 in 2016.

Acknowledgements

The OMERACT working group:

Co-chairs: Oliver FitzGerald, Dafna Gladman, Philip Helliwell, Philip Mease

OMERACT liaison: Vibeke Strand

Fellows: William Tillett, Lihi Eder

Patient Research Partners: Maarten de Wit, Ina Campbell, Niti Goel

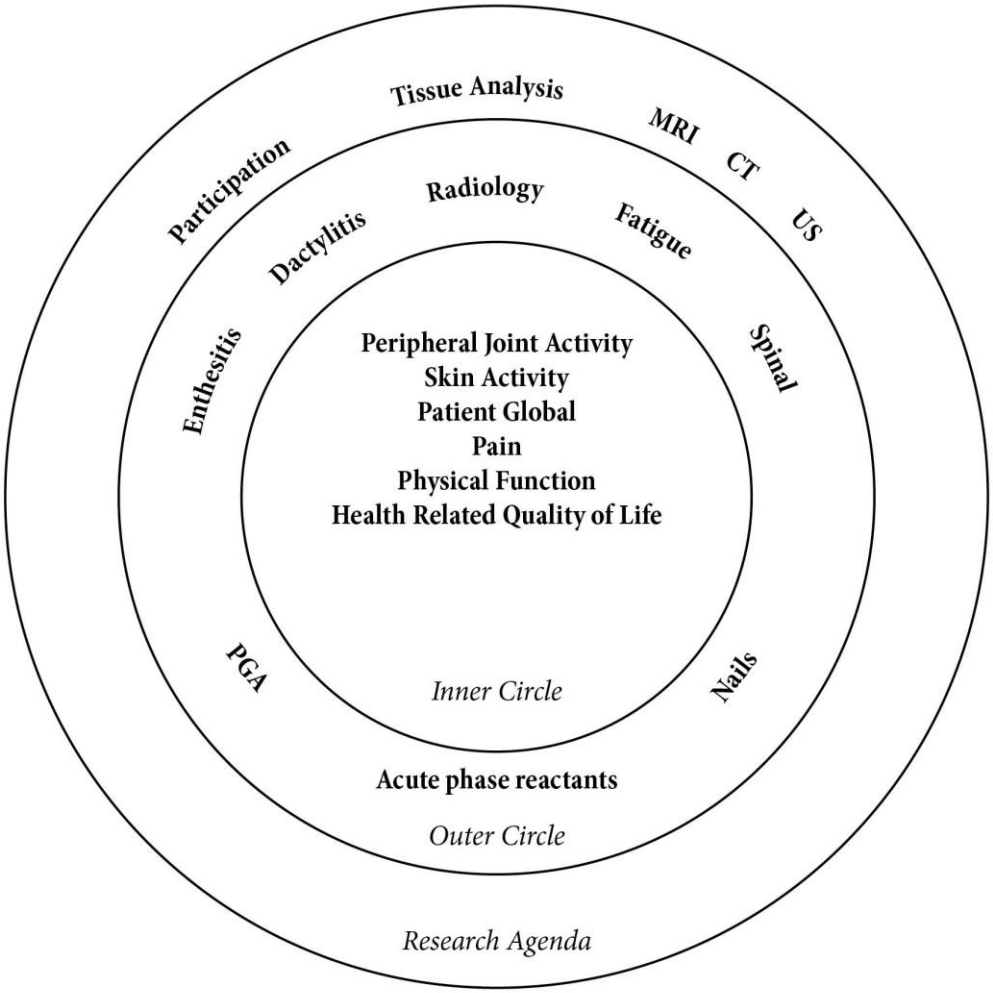
GRAPPA attendees: Alexis Ogdie, Anna-Maria Orbai

References

1. Gladman DD, Mease PJ, Strand V, Healy P, Helliwell PS, Fitzgerald O, et al. Consensus on a core set of domains for psoriatic arthritis. J Rheumatol 2007;34:1167-70.
2. Coates LC, Fitzgerald O, Mease PJ, Gladman DD, Strand V, Goel N, et al. Development of a Disease Activity and Responder Index for Psoriatic Arthritis -- Report of the Psoriatic Arthritis Module at OMERACT 11. J Rheumatol 2014;41:782-91.
3. Mease PJ. Measures of psoriatic arthritis: Tender and Swollen Joint Assessment, Psoriasis Area and Severity Index (PASI), Nail Psoriasis Severity Index (NAPSI), Modified Nail Psoriasis Severity Index (mNAPSI), Mander/Newcastle Enthesitis Index (MEI), Leeds Enthesitis Index (LEI), Spondyloarthritis Research Consortium of Canada (SPARCC), Maastricht Ankylosing Spondylitis Enthesis Score (MASES), Leeds Dactylitis Index (LDI), Patient Global for Psoriatic Arthritis, Dermatology Life Quality Index (DLQI), Psoriatic Arthritis Quality of Life (PsAQOL), Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F), Psoriatic Arthritis Response Criteria (PsARC), Psoriatic Arthritis Joint Activity Index (PsAJAI), Disease Activity in Psoriatic Arthritis (DAPSA), and Composite Psoriatic Disease Activity Index (CPDAI). Arthritis Care Res (Hoboken) 2011;63 Suppl 11:S64-85.
4. OMERACT. Guiding principles for patient research partner participation in OMERACT. [27 March 2011; cited 08 January 2015]; Available from: http://www.omeract.org/pdf/2011-03-27%20Agreed%20Patient%20Participation%20Policy.pdf.
5. OMERACT Handbook. [July 2014; cited 08 January 2015]; Available from: http://www.omeract.org/pdf/OMERACT_Handbook.pdf.
6. Bingham CO, 3rd, Alten R, de Wit MP. The importance of patient participation in measuring rheumatoid arthritis flares. Ann Rheum Dis 2012;71:1107-9.
7. De Wit M, Abma T, Koelewijn-van Loon M, Collins S, Kirwan J. Involving patient research partners has a significant impact on outcomes research: a responsive evaluation of the international OMERACT conferences. BMJ open 2013;3.
8. de Wit MP, Berlo SE, Aanerud GJ, Aletaha D, Bijlsma JW, Croucher L, et al. European League Against Rheumatism recommendations for the inclusion of patient representatives in scientific projects. Ann Rheum Dis 2011;70:722-6.
9. Tillett W, Adebajo A, Brooke M, Campbell W, Coates LC, FitzGerald O, et al. Patient involvement in outcome measures for psoriatic arthritis. Curr Rheumatol Rep 2014;16:418.
10. Gossec L, de Wit M, Kiltz U, Braun J, Kalyoncu U, Scrivo R, et al. A patient-derived and patient-reported outcome measure for assessing psoriatic arthritis: elaboration and preliminary

validation of the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire, a 13-country EULAR initiative. Ann Rheum Dis 2014;73:1012-9.
11. Tillett W, Eder L, De Wit M, Gladman D, FitzGerald O, N G, et al. Enhanced patient involvement and the need to update the psoriatic arthritis core set- report from the Psoriatic Arthritis workshop at OMERACT 2014. Journal of Rheumatology 2014;(in press).
12. Coates LC, FitzGerald O, Gladman DD, McHugh N, Mease P, Strand V, et al. Reduced joint counts misclassify patients with oligoarticular psoriatic arthritis and miss significant numbers of patients with active disease. Arthritis Rheum 2013;65:1504-9.
13. Helliwell PS, Firth J, Ibrahim GH, Melsom RD, Shah I, Turner DE. Development of an assessment tool for dactylitis in patients with psoriatic arthritis. J Rheumatol 2005;32:1745-50.
14. Gladman DD, Inman RD, Cook RJ, Maksymowych WP, Braun J, Davis JC, et al. International spondyloarthritis interobserver reliability exercise--the INSPIRE study: II. Assessment of peripheral joints, enthesitis, and dactylitis. J Rheumatol. 2007;34(8):1740-5.
15. Chandran V, Bhella S, Schentag C, Gladman DD. Functional assessment of chronic illness therapy-fatigue scale is valid in patients with psoriatic arthritis. Ann Rheum Dis 2007;66:936-9.
16. Chandran V, Gottlieb A, Cook RJ, Duffin KC, Garg A, Helliwell P, et al. International multicenter psoriasis and psoriatic arthritis reliability trial for the assessment of skin, joints, nails, and dactylitis. Arthritis Rheum 2009;61:1235-42.
17. de Wit M, Campbell W, FitzGerald O, Gladman DD, Helliwell PS, James J, et al. Patient participation in psoriasis and psoriatic arthritis outcome research: a report from the GRAPPA 2013 Annual Meeting. J Rheumatol 2014;41:1206-11.
18. de Wit M, Campbell W, Orbai A-M, Tillett W, FitzGerald O, Gladman DD, et al. Building Bridges between Researchers and Patient Research Partners: A Report from the GRAPPA 2014 Annual Meeting. J Rheumatol 2015, submitted.
19. Boers M, Kirwan JR, Wells G, Beaton D, Gossec L, d'Agostino MA, et al. Developing core outcome measurement sets for clinical trials: OMERACT filter 2.0. J Clin Epidemiol 2014;67:745-53.
20. Gladman DD, Ziouzina O, Thavaneswaran A, Chandran V. Dactylitis in psoriatic arthritis: prevalence and response to therapy in the biologic era. J Rheumatol 2013;40:1357-9.
21. Walsh JA, McFadden ML, Morgan MD, Sawitzke AD, Duffin KC, Krueger GG, et al. Work productivity loss and fatigue in psoriatic arthritis. J Rheumatol 2014;41:1670-4.
22. Sakkas LI, Alexiou I, Simopoulou T, Vlychou M. Enthesitis in psoriatic arthritis. Semin Arthritis Rheum 2013;43:325-34.

Figure 1: Domains for PsA. (Reproduced with kind permission from The Journal of Rheumatology)(1)



CT = Computed Tomography; MRI = Magnetic Resonance Imaging; PGA = Physician Global Assessment; US = Ultrasound

Figure 2: Conceptual framework for core areas. (Reproduced with kind permission)(19)