

The GRAPPA-OMERACT Psoriatic Arthritis Working Group at the 2018 Annual Meeting: Report and Plan for Completing the Core Measurement Set

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ABSTRACT: The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA)-Outcome Measures in Rheumatology (OMERACT) Psoriatic Arthritis (PsA) working group reported at the 2018 GRAPPA annual meeting on the outcome of the OMERACT 2018 Conference in Terrigal, Australia. The working group presented the endorsement of the 66/68 joint count for the assessment of peripheral arthritis and the provisional endorsement of the PsA Impact of Disease 12 (PSAID12) questionnaire for the assessment of PsA-specific Health-Related Quality of Life in PsA randomised controlled trials and observational studies. In this report, the group presents its plan to seek OMERACT endorsement for outcome measures that address the domains of physical function and structural damage following the OMERACT filter 2.1 methodology.

Key Indexing Terms: Psoriatic Arthritis, Psoriasis, Outcome Measures, GRAPPA, OMERACT

Source of Support: YYL is funded by the Clinician Scientist award of the National Medical Research Council, Singapore (NMRC/CSA-INV/0022/2017). The views

expressed are those of the author(s) and not necessarily those of the NMRC. LCC is funded by a National Institute for Health Research Clinician Scientist award. The research was supported by the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (BRC). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR, or the Department of Health. AO is funded by the Rheumatology Research Foundation and NIH/NIAMS K23 AR063764 and R01 AR072363. AMO is funded by the Jerome L. Greene Foundation Scholar Award, the Staurulakis Family Discovery Award, the Rheumatology Research Foundation, and the National Institutes of Health (NIH) through the Rheumatic Diseases Resource-based Core Center (P30-AR053503 Cores A and D, and P30-AR070254, Cores A and B). All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of the NIH, the National Institute of Arthritis Musculoskeletal and Skin Diseases (NIAMS), or the Rheumatology Research Foundation (RRF).

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Running Footline: GRAPPA-OMERACT Core Measurement Set

Word count: 1882 words, including abstract (117), text (1326), and references (439;
n=12), but excluding the title page

Introduction

In 2018, the Outcome Measures in Rheumatology (OMERACT) updated and outlined a conceptual framework for core set development (Filter 2.1) that encompasses both patient-centred and intervention-specific information to improve the measurement of outcomes in randomised controlled trials (RCTs) and longitudinal observational studies (LOS).(1) The OMERACT Filter 2.1 has also distinguished two major components in outcome research, namely, determining “what to measure” before deciding on “how to measure”. This two-stage process comprises the development of a “Core Domain Set” that identifies domains of disease to be measured and then develops a “Core Outcome Measurement Set” that selects measurement instruments to match the domains of disease.(2)

In 2016, the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA)-OMERACT Psoriatic Arthritis (PsA) Core Set working group updated the Core Domain Set for all RCTs and LOS.(3, 4) The updated PsA Core Domain Set includes musculoskeletal (MSK) disease activity (peripheral arthritis, enthesitis, dactylitis, and axial symptoms), skin disease activity (including nails), pain, patient global, physical function, health-related quality of life, fatigue, and systemic inflammation, with structural damage as a middle-circle domain required once during the development program of a PsA treatment.(4)

After the GRAPPA-OMERACT PsA working group established the Core Domain Set, it began to develop a PsA Core Outcome Measurement Set.(5) In 2018, the working group was the first disease group to take an outcome measure of physical examination and a patient-reported outcome measure (PROM) through the OMERACT Filter 2.1 and obtain the OMERACT community’s endorsement of the

66/68 joint count and PsAID12.(6, 7) This is a report of the working group's presentation at the GRAPPA 2018 annual meeting in Toronto, Ontario, Canada, where the process and voting outcomes from the 2018 OMERACT meeting in Terrigal, Australia, were presented to the GRAPPA membership, and the next steps in completing the Core Outcome Measurement Set using OMERACT methodology were defined.

Summary of the first two instruments endorsed for PsA trials

Dr. Alexis Ogdie and Dr. Ana-Maria Orbai presented Filter 2.1 methodology that seeks to evaluate each instrument using the four pillars of OMERACT,(2) which include truth 1 (domain match), feasibility, truth 2 ("numerical sense"), and discrimination (Figure 1):

1. Truth 1, Domain Match: Is an instrument a good match to the domain intended to be measured?
2. Feasibility: How feasible is the instrument to use?
3. Truth 2, "Numerical Sense": How truthfully does the instrument numerically match the domain or construct?
4. Discrimination: How responsive is the instrument to capture change in disease status?

Dr. Ogdie and Dr. Orbai presented the group's evaluation of the existing evidence on PsA instrument properties through systemic literature reviews and data analyses from RCTs, followed by Delphi processes undertaken in partnership with stakeholders (including patients, clinicians, methodologists, and payers), working group meetings, and discussion. The following is a summary of the data presented.

The GRAPPA-OMERACT group has conducted a comprehensive systematic literature review (SLR) of measurement properties of PROMs for PsA,(8) which serves as the basis for instrument selection. To take instruments through the new OMERACT Filter 2.1 appraisal, the group decided to concentrate on one physical examination instrument, the 66/68 swollen and tender joint counts, and one PROM, the PsA Impact of Disease (PsAID12), for measuring domains of MSK disease activity (peripheral joints) and health-related quality of life, respectively. Each instrument was evaluated by stakeholders including health care providers and patients for domain match and feasibility. Measurement properties of truth and discrimination for both instruments were critically appraised. A post-hoc analysis of data from RCTs was performed for the 66/68 joint counts. Data from two longitudinal cohorts(9, 10) in patients with active PsA who experienced changes in treatments were evaluated to support the longitudinal construct validity for the PsAID12. Data were not yet available from RCTs for the PsAID12, as the PsAID12 was recently developed in 2014 and data uptake lag is expected. Evidence was consolidated in the OMERACT summary of measurement properties (SOMP) tables and presented at the OMERACT 2018 conference in Terrigal, Australia.(6, 7) The 66/68 joint count was fully endorsed as the PsA core instrument. Due to lack of data from RCTs, the PsAID12 received provisional endorsement as the PsA core instrument. The working group is committed to deriving evidence that may confirm discrimination for the PsAID12.

Future work plan

Domains prioritized for instrument appraisal. The GRAPPA-OMERACT working group will continue to work on the appraisal of instruments for each domain in the core set. The prioritized domains comprise MSK disease activity for enthesitis and

dactylitis, physical function, fatigue, and structural damage. These domains were chosen due to their importance in clinical trials and the urgent need to standardize instruments that evaluate these domains, or because the relevant systematic review for instruments for the particular domain has been completed. Thus far, the working group has completed SLRs of all PROMs(8) and of systemic inflammation(11) with other SLRs in progress. Additional core domains (pain, patient global, and skin disease activity) are being evaluated as part of dedicated working groups within OMERACT and International Dermatology Outcome Measures (IDEOM).

Selection of instruments for individual domains. The OMERACT Filter 2.1 has given clear guidance of appraisal and evidence synthesis for individual instruments. However, it is common that numerous instruments exist for a particular domain. For the selection of one or more appropriate instruments for appraisal, the working group has developed an instrument selection guide to facilitate the process (Figure 2). This guide consists of:

1. Formation of a working group for the particular domain. The domain working group members preferably consist of care providers or personnel with a track record or expertise in the domain. Each domain working group should involve at least 2 patient research partners (PRPs) with personal experience in the disease under study who are aware of their role and understand the OMERACT methodology.
2. Initial literature search and appraisal of instruments for the domain under investigation.
3. Domain working group discussion of the rationale to include or exclude an instrument.

4. Delphi consensus exercise to determine the instrument(s) to include.
Up to 2 rounds of Delphi exercise for instrument selection are recommended, with interim discussions following each on rationale among working group members. The group will pilot this instrument selection process for the physical function domain.

Composite indices. Composite indices are commonly used in rheumatology for the assessment of disease activity and disease impact, as well as for defining a treatment target or disease state (e.g., remission). These indices typically span across several domains to encompass a broader concept of disease activity including defining responders to treatment. Over the past decade, several composite indices have been developed specifically for PsA and used in RCTs.(12) The composite indices commonly used for PsA are summarized in Table 1. Despite the prominent use of composite measures, the process for validation of these measures is not yet clear. A proposal has been made for a workstream within OMERACT to address this process. Key members of the GRAPPA-OMERACT group will contribute to this process and develop consensus on how to validate these measures.

Conclusion

It is the GRAPPA-OMERACT PSA working group's objective to seek OMERACT's endorsement of a full set of outcome measures that reflects the entire PsA Core Domain Set to facilitate comparison across clinical trials and collaboration between researchers in the PsA field. The working group has completed the process using the OMERACT 2.1 filter to obtain OMERACT's endorsement of the first two instruments for the PsA Core Outcome Measurement Set. In addition, the working

group has proposed a prioritized list of domains for instrument appraisal and a structure for the initial selection of instrument(s) for domains, while also highlighting the need for new guidelines to appraise composite indices.

Acknowledgements: The GRAPPA-OMERACT PSA working group would like to acknowledge the support of GRAPPA, as well as Pam Love for her organizational efforts in supporting the working group's meetings. The working group would also like to acknowledge those working group members who were unable to attend the 2018 GRAPPA annual meeting.

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