The GRAPPA-OMERACT Psoriatic Arthritis Working Group at the 2019 Annual Meeting: Updates on the 4 prioritized Domains for Completing the Core Outcome Measurement Set

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Please see if I have missed out anyone.
Or anyone that we should get them into steering committee too?

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Running Footline: GRAPPA-OMERACT Core Measurement Set

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Word count: xx words, including abstract (xx), text (xx), and references (xx; n=xx), but excluding the title page

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. 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). AO is funded by the Rheumatology Research Foundation and NIH/NIAMS K23 AR063764 and R01 AR072363. 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.

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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 2019 GRAPPA annual meeting on updates on the work towards a Core Outcome Measurement Set for PsA. Four domains have been prioritized including MSK disease activity (enthesitis and dactylitis), fatigue, physical function, and structural damage. Updates of the work progress of each domain were summarized.

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Key Indexing Terms:

Psoriatic Arthritis, Psoriasis, Outcome Measures, GRAPPA, OMERACT

Introduction

The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA)-Outcome Measures in Rheumatology (OMERACT) Psoriatic Arthritis (PsA) Core Set working group has updated the Core Domain Set in 2016 (1, 2). The updated PsA Core Domain Set developed through a combined effort of health care professionals and patient research partners (PRPs), defined domains that are essential to be measured in all clinical trials (1, 2). Since then, the working group has begun the work to develop a PsA Core Outcome Measurement Sets (3). At OMERACT in 2018, the 66/68 swollen and tender joint counts received endorsement for the measurement of "musculoskeletal (MSK) disease activity: peripheral joints" (4) and the PsAID12 received provisional endorsement for the domain of health related quality of life (5).

Four domains have been prioritized for appraisal of the instruments, including MSK disease activity (enthesitis and dactylitis), fatigue, physical function, and structural damage. These 4 domains were chosen due to their importance in clinical trials and the urgent need to standardize instruments for the domains (6). This is a report of the working group's presentation at the GRAPPA 2019 annual meeting in Paris, France where the work undertaken in standardizing the Core Outcome Measurement set for these 4 domains was presented.

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The overall work stream for each domain

Dr Leung explained briefly that the appraisal of instruments for each domain follows the methodology lay out by the OMERACT Filter 2.1(6). The four pillars of the OMERACT Filter 2.1 consist of Truth 1 (Domain match), Feasibility, Truth 2 (Numerical sense) and Discrimination (7). The overall work stream plan for each of the 4 domains starts with

conveying a domain working group. Members of each domain working group comprise of health care professions with relevant expertise and at least 2 PRPs. Relevant instrument(s) for the domains will then be identified via systematic literature reviews. For domains that have numerous instruments available, the domain working groups may prioritize instruments through discussion and Delphi exercises to achieve consensus. Prioritized instruments for a domain would then be critically appraised using the OMERACT Filter 2.1. For some instruments, missing evidence may need to be identified. The working group has already developed and used specific methods for evaluating domain match by patient research partners. The appraisal processes with the OMERACT Filter 2.1 will be discussed with the OMERACT technical advisory group. The evidence supporting each instrument for a particular domain will be provided in the OMERACT summary of measurement properties table. The domain working groups will consider the evidence supporting each instrument and develop consensus via Delphi exercises. All documents derived for each instrument will be submitted to OMERACT for further endorsement. A new virtual voting method from OMERACT will be available that enables endorsement of instruments from the OMERACT community, rather than the standard voting workshop during the 2-yearly OMERACT congress.

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Oliver: Yes. Collected

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Updates on work stream for each prioritized domain

MSK: Disease Activity: Enthesitis and Dactylitis

The MSK disease activity working group was led by Alexis Ogdie and included 3 PRPs. The working group completed a systematic literature review of the instruments measuring dactylitis, enthesitis, and peripheral joint counts in March 2017. The summary from the peripheral joint studies has now been published (4). Since OMERACT 2018, the working group has been assembling similar summaries of the measurement property tables

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for enthesitis and dactylitis. Fewer studies have investigated the psychometric properties of these disease features. Next steps will include a similar Delphi exercise to that performed for the joint counts and will also include patient engagement so as to understand the content validity of the measures of enthesitis and dactylitis from the patient perspective.

Enthesitis can also be assessed using ultrasound. An independent working group, led by Lihi Eder, has been focussing on the measurement properties of sonographic assessed enthesitis and the group has performed a systematic literature review (SLR) on sonographic enthesitis scoring instruments for the assessment of enthesitis (8). A few sonographic enthesitis scoring instruments which were developed for spondyloarthritis have been identified but most have not been validated in PsA. None of these instruments has the potential to pass the OMERACT filter 2.1. Therefore, additional research is required before existing instruments for assessing enthesitis on ultrasound can be endorsed.

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I drafted this for you. Can you refine. Thanks.

Physical Function

The physical function working group consisted of 13 members including 2 PRPs. The working group has international representation that spans across America, Asia and Europe. Based on data from a published SLR on patient-reported outcome measures (PROMs) in PsA (9), the working group has identified a list of PROMs that measure physical function for PsA. Additional newer instruments were recommended by working group members. Through discussions and two rounds of Delphi exercises, the working group has prioritized 6 patient PROMs. Each of these PROMs will be further appraised individually using the OMERACT Filter 2.1. These 6 PROMs are the Health Assessment Questionnaire (HAQ)– Disability index (DI), HAQ -Spine (S), modified (m) HAQ, multidimensional (MD) HAQ, the physical functioning domain of the Medical Outcome Survey Short Form – 36 (SF-36-PF) and Patient-Reported Outcomes Measurement Information System – physical function (PROMIS-

PF). The working group is working on a SLR evaluating the RCT discrimination of various PROMs for physical function.

The appraisal document for HAQ-DI has been submitted to OMERACT for virtual voting. The SF-36-PF will be appraised next. The other PROMs will require synthesis of new data before formal appraisal using the OMERACT Filter 2.1.

Fatigue

Fatigue is a PsA core domain that is variably measured in PsA clinical trials (10).Evidence supporting fatigue instruments in PsA has been summarized in the above mentioned systematic literature review in PROMs (9). The instruments that had psychometric evidence in PsA were FACIT-Fatigue, Fatigue visual analog scale (VAS), Fatigue numerical rating scale (NRS), and the Vitality component of the SF-36 form. New evidence has emerged for fatigue instruments in PsA since the publication of the SLR including RCT thresholds for improvement for FACIT-Fatigue and the Fatigue NRS (11) as well as the FACIT-Fatigue content validity. A challenge for the appraisal of VAS and NRS single items is the standardization of the wording and time interval (past 7 days, today). A Fatigue working group led by Dr Orbai has been convened The Fatigue working group will consider the fatigue instruments as identified above (9), instruments used in prior PsA studies such as Fatigue Severity Score, Fatigue Assessment Scale, PROMOS-Fatigue and single fatigue-items included in the BASDAI and PsAID questionnaires (10). Similar to the prioritization process undertaken for the Physical Function domain, the working group will use discussion and Delphi exercises to prioritize instruments which will undergo further evaluation using the OMERACT Filter 2.1.

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Structural Damage

Dr Tillett and Dr Antony reviewed progress from the structural damage group. Unlike domains in the inner circle which are mandatory in all RCTs, the assessment of structural damage is placed in the middle circle of the core domain set where inhibition of structural damage is seen as important to be demonstrated at least once during drug development but not required to be measured in all clinical trials (2). As a result, structural damage has been prioritized by the OMERACT working group for selection of measurement instruments despite its position in the middle circle of the core domain set. The structural damage working group is conducting a SLR of imaging instruments for the assessment of structural damage in PsA. The group discussed how the literature review data should be reported and it was agreed that data relating to plain radiographic instruments would be reported first followed by the other imaging modalities including Magnetic Resonance Imaging, Ultrasound and Computed Tomography.

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Actually, according to the new model of the onion, structural damage fits perfectly in the newly developed category in the inner circle as : mandatory under specific circumstances.
Not appropriate now for this short report, but we should keep this in mind for future updates of the core domain set.

Composites

Composite indices are commonly used in rheumatology for the combined assessment of disease as well as for defining a treatment target or disease state. They typically span across several domains to encompass a broader concept of disease activity and disease impact. Several composite indices have been developed specifically for PsA and used in RCTs (12), but no consensus has been achieved of on which instrument to take forward (13). and the process for validation of composite indices is yet to be clarified within OMERACT. A workshop on composite indices in PsA was undertaken at the GRAPPA annual meeting and it is reported separately.

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I drafted this. Please help refine.

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Conclusion

This report summarized the work progress of GRAPPA-OMERACT PsA Core Set working group in a combined effort to a standardized Core Outcome Measurement Set. We have described an additional four prioritized domains including MSK disease activity (enthesitis and dactylitis), fatigue, physical function, and structural damage and we have reported on the progress of each working group for each domain.

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