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Assessment of the many faces of PsA: single and composite measures in PsA clinical trials

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Abstract

PsA is a complex, heterogeneous disease that can place a large burden on patients' psychological and physical well-being. The multifaceted nature of PsA poses a significant assessment challenge, both in randomized control trials and in clinical practice. In recent years, there has been much progress in the development of unidimensional and composite measures of disease activity, as well as of questionnaires that capture the patient's perspective of the condition. Despite these advances, there remains uncertainty around which tools to implement within a research setting. This review aims to summarize the currently available clinical and patient-derived assessment tools, providing a practical and informative resource for the assessment of PsA. This review will also explore recent advancements in digital approaches to the assessment of rheumatological conditions. This will highlight the potential for digitalization in the assessment and monitoring of PsA, outlining innovative means of capturing disease activity and treatment response.

Key words: composite measures, disease activity, impact of disease, outcome measures, patient perspective, psoriatic arthritis, mobile health, health information technology

Rheumatology key messages

- A number of single-domain and composite outcome measures are utilized in PsA clinical trials.
- The variety of assessments reflects the multifaceted nature of PsA and can answer different questions.
- Future digitalization of outcomes may change assessment of disease activity and patient impact in PsA.

REVIEW

Introduction

PsA is a multifaceted inflammatory musculoskeletal disease comprising several domains, including peripheral arthritis, enthesitis, dactylitis, axial disease and psoriasis. Due to the heterogeneity in the clinical presentation of PsA, assessing disease activity in the context of clinical practice and research trials has proven a challenge. In addition to physician-assessed measures of disease activity, the patient perspective on the impact of their condition, through patient-reported outcomes (PROs) tools, is also a key component of assessment. These tools provide insight into wider aspects of the condition, encompassed under pain, fatigue, loss of function, and impact on quality of life (QoL). Assessment of these varied outcomes can allow us to assess response in both observational and interventional trials.

This review will appraise the advantages and limitations of both single-domain and composite outcome measures utilized in clinical trials in PsA, while also looking at the potential for novel assessment modalities, particularly in the area of electronic data capture.

Single-domain measures

Arthritis

All current measures of peripheral arthritis are based on the measurement of tender and swollen joint counts, in combination with some PROs, as a composite measure. Given the broad heterogeneity in the distribution of joints affected in PsA, a more comprehensive 68/66 joint count is required.

Early attempts at classifying disease activity relied heavily on measurement tools validated in other inflammatory joint diseases. Many studies in PsA populations have employed the DAS 28 (initially developed for RA) to measure arthritis. Importantly, the reduced joint counts of the

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DAS is concerning and does not capture joints commonly affected in PsA, potentially underestimating key components of disease activity in many patients with PsA, especially in oligoarthritis affecting the DIP joints or feet.

The ACR 20% response criteria has proved a mainstay in measuring primary outcomes in randomized control trials (RCTs). The ACR response criteria, also developed for research trials in RA, has been modified to employ a 68/66 joint count for PsA studies. The ACR criteria is a binary outcome for those who achieve a 20%, 50% or 70% reduction in tender and swollen joint counts, plus three of the following: physician global, patient global, patient pain, function and CRP/ESR. While these measures are effective at differentiating intervention from placebo in polyarticular patients [1], there are floor effects in patients with lower joint counts at baseline, and these patients may struggle to achieve significant response levels as a result [2]. For this reason, the ACR criteria may not be a suitable outcome measure for trials that follow a pragmatic design, in which patients are perhaps more representative of clinical practice, and therefore include lower joint counts. However, this has not been explored in any detail in PsA.

An adaptation of the Disease Activity Index for Reactive Arthritis (DAREA) scale, renamed the Disease Activity Index for Psoriatic Arthritis (DAPSA), was developed from a clinical cohort of PsA patients [3] and subsequently validated in a clinical trial setting [4]. The DAPSA was the first validated measurement tool designed specifically for PsA. It incorporates a 68/66 joint count, a patient global assessment, a patient assessment of pain, and CRP to give a composite measure of disease activity and treatment response. This is expressed as a score of arthritis activity and has validated cut-off points for response (50, 65 and 85% reductions in DAPSA score) and for levels of disease activity such as low disease activity ($<$14) and remission ($<$4). The DAPSA responses were established in reference to the ACR response rates, but have not been utilized in many studies to date. The DAPSA scores, responses and thresholds make it a potentially useful tool in a clinical trial setting, tracking response in arthritis to interventions [5]. However, due to its dependence on the 68/66 joint counts, the DAPSA, like the ACR criteria, is less useful in defining treatment response for patients who have lower joint counts or oligoarthritis.

Psoriasis/skin

The most commonly used outcome measure in psoriasis clinical trials is the Psoriasis Area and Severity Index (PASI). The PASI requires detailed assessment of body surface area, erythema, induration, and scaling of psoriasis separately for four regions on the body (head, trunk, upper limbs and lower limbs) [6]. This comprehensive measure of skin, although the gold standard for assessment of severe psoriasis, is particularly burdensome to complete owing to its multiple components. A major limitation of the PASI is that it is not routinely used by clinicians outside of research settings, and therefore is poorly understood by both clinicians and patients alike. The PASI also lacks sensitivity in patients with lower disease activity.

Attempts to reduce the workload involved in measuring skin features have led to the recent development of the static Physician Global Assessment $\times$ body surface area [7]. The static Physician Global Assessment, recorded on a scale of 1 (clear) to 6 (severe), measures plaque quality in a more general sense than the PASI, without assessing total surface coverage. The static Physician Global Assessment is then combined with the body surface area to give a composite measure of skin disease. It is thought that this more user-friendly tool will allow assessment of characterization of skin plaques with a wider surface coverage. Early validation has shown that there is good concordance with the PASI [8], and it will be interesting to see whether this assessment tool transfers to clinical trials in PsA and psoriasis.

Enthesitis

Further recognition of the importance of individual manifestations of disease activity in PsA led to the development of two validated clinical measures of enthesitis: the Leeds Enthesitis Index (LEI) and the Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score. Prior to this, a scoring tool, the Maastricht Ankylosing Spondylitis Enthesitis Score was used in clinical trials for patients with PsA. The LEI was designed specifically for PsA, and measures tenderness at three sites bilaterally (lateral epicondyles of the humerus, medial condyles of the femur, and Achilles tendons) [9]. The sites included in the SPARCC tool were chosen based on radiographic evidence of enthesitis in SpA (PsA and AS). The LEI focuses on peripheral sites of enthesitis, in comparison with the SPARCC score, which factors in some 16 sites bilaterally, including common central sites of enthetitis seen in AS. These tools are routinely implemented in RCTs for PsA, with no superiority between the LEI and SPARCC tools as yet identified. However, they were both found to be superior in terms of discriminatory capacity when compared with the Maastricht Ankylosing Spondylitis Enthesitis Score [10]. Importantly, enthesitis is assessed clinically, by physical examination of tenderness at the entheseal site. For this reason, it is a nonspecific finding with questions over its face validity. The presence of tenderness does not denote active inflammation, and may be confounded by concomitant fibromyalgia. Similarly, its absence does not rule out enthesitis. Attempts to strengthen the face validity of the assessment of enthesitis in clinical trial settings have led to studies including additional imaging modalities, largely US.

Dactylitis

Dactylitis is characterized by swelling of a whole digit and represents a combination of inflammation of tendon and ligament insertions and synovitis. It is a hallmark feature of PsA, and occurs in 16–48% of reported cases [11]. The simplest means of assessing dactylitis is through simple counts of dactylitic digits, and this has been employed in the majority of studies in PsA. This can be carried out in a

semi-quantitative way by multiplying the number of dactylitic digits with a 0–3 tenderness grading used in the Ritchie Index. Although convenient, simple digit counts are dependent on user experience and on often subtle appreciation of dactylitis. As a result, a more objective and reproducible tool, the Leeds Dactylitis Instrument, has been developed, largely for clinical research purposes [12]. A dactylometer measures the circumference of swollen digits at the base, and this is then compared with the contralateral digit or a population norm-referenced value, if digits are bilaterally swollen. This provides a quantifiable and specific measure of dactylitis; defined as a minimum difference in digit circumference of 10%. The Leeds Dactylitis Instrument then combines this circumference measurement with a score for digit tenderness, again ranked 0–3 from the Ritchie index, or simply a dichotomous 0–1 (0 = non-tender, 1 = tender). The Leeds Dactylitis Instrument score has been shown to be responsive in clinical trials and has a larger effect size than simple dactylitis counts, making it a useful tool in trials with smaller sample sizes [12, 13].

Axial disease

Axial disease, present in some 20–50% of patients with PsA, with potentially significant effects on mobility and function has proved a relative assessment challenge in PsA cohorts. In clinical practice, outcome tools for use in axial PsA have all been adopted from AS. The BASDAI has been employed, but although correlating with measures of disease activity it has poor resolution in terms of differentiating axial from peripheral disease activity. Its inability to differentiate individual domains of disease activity has largely limited its use to clinical practice.

Composite disease activity measures

Given the heterogeneous nature of PsA, there are significant difficulties in assessing the multiple domains of the condition in isolation. Attempts to corroborate the individual aspects of the condition and assess the many faces of PsA have produced a number of composite assessment tools, which give an overall impression of disease severity. These will now be reviewed in detail.

The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) aimed to address the nuanced and complex nature of PsA by establishing a treatment grid of core features that should be included in the overall assessment of the disease [14]. This work served as the cornerstone for the first disease activity composite measure for PsA, the Composite Psoriatic Disease Activity Index (CPDAI) [15]. The CPDAI involves assessment of each domain of PsA; [peripheral joints (68/66 joint count), skin (PASI), entheses, dactylitis (simple digit count), and axial disease] in terms of disease activity and overall disease impact on patients' function and health-related QoL. These values are then summed together to a score between 0–15. A performance comparison of the CPDAI and DAPSA in the Psoriasis Randomised Etanercept STudy in Subjects with Psoriatic Arthritis (PRESTA) trial dataset confirmed the ability of the CPDAI to measure changes to skin and aspects beyond the articular presentation, and subsequently discriminate between different doses of etanercept [16].

Another international GRAPPA working group developed two further composite indices through a project called GRAPPA Composite Exercise (GRACE). This study established a longitudinal cohort of 503 patients with PsA and collected a large range of clinical data and PROs at baseline, 3, 6 and 12 months. At each visit, treatment changes were noted, with physician decision to escalate treatment being used as a surrogate for an active disease state. The PsA DAS was developed by multiple linear regression analysis of the GRACE cohort to determine the weighted index of each constituent domain [17]. The PsA DAS incorporates patient and physician global visual analogue scale scores, tender and swollen joint counts, dactylitis and enthesitis, health-related QoL, and CRP level. The GRACE index contains eight domain measures transformed using desirability functions and then combined together [17]. Both of these measures have been validated in the GRACE cohort [17], and have been shown to be effective in retrospective *post-hoc* analysis of previous RCTs [18], including correlation with PROs [19] and radiographic progression [20]. The overall effect sizes of these tools were greater than the DAPSA, CPDAI and DAS28, meaning that smaller sample sizes may be needed for future trials. As more therapies gain market approval in PsA, it will become increasingly difficult to justify the randomization of patients with active disease into a placebo arm, further highlighting the importance of these composite indices in pragmatic RCTs.

Composite measures such as these offer the assessment of overall response to therapy across multiple domains. However, it should be noted that in trials it is beneficial to include a combination of composite and individual domain measures to assess overall response to a therapy and to identify response within specific domains of disease.

Target of therapy

A treat-to-target approach for PsA was first advocated by EULAR in 2015 [21], following results from the TIght Control of PsA [22]. This was the first study in PsA to confirm the benefit of treating to target using the minimal disease activity (MDA), with improved clinical and PROs despite increased adverse drug-related events [22]. The MDA criteria encompass seven different items that are assessed individually. According to the MDA criteria, patients are in MDA if they achieve 5 out of the following 7: tender joint count $\leqslant 1$, swollen joint count $\leqslant 1$, enthesitis count $\leqslant 1$, PASI $\leqslant 1$ or body surface area $\leqslant 3$, patient global visual analogue scale $\leqslant 20$ mm, patient pain visual analogue scale $\leqslant 15$ mm and HAQ $\leqslant 0.5$ [23].

Consensus has been reached that remission of disease activity should be the primary target in the treatment of PsA [24]. An international treat-to-target taskforce supported DAPSA remission/low disease activity (LDA), with MDA as an acceptable alternative, as the target for

treatment in PsA trials [25]. The MDA criteria is a composite measure that assesses all of the various domains of PsA, in order to capture disease state, whereas the DAPSA, as previously outlined, is a unidimensional tool that focuses on the articular manifestations of PsA and fails to account for the other disease domains. A recent head-to-head analysis comparing disease burden of PsA in patients with LDA according to the two definitions MDA and DAPSA-LDA found that there was evidence of better QoL in patients who satisfied the MDA criteria than in those who reached DAPSA-LDA only [26]. The MDA is a binary measure and for this reason, once achieved as a target, it does not show changes in disease activity, although changes in the individual items within MDA can be tracked over time. Further studies are needed to assess which of these outcomes is the best target in the treatment of PsA; however, the early evidence would suggest that displaying LDA across the many domains of PsA is more appropriate in clinical practice, where the increased ease of use for the assessor will reduce interobserver error across all members of the care team.

PROs—measuring the patient perspective

In recent years, there has been an increased emphasis on the importance of capturing the patient perspective in the overall assessment of disease activity across all disciplines of medicine. In rheumatology, the integration of patient experts into the GRAPPA-OMERACT working group has led to the addition of patient-specific domains within the core set. These include measurements of pain, fatigue and overall functioning to give an appreciation of the wider psychosocial impacts of the condition. A variety of patient-reported tools have been developed in PsA, and although focusing on disease impact over disease activity, these differing constructs are not mutually exclusive. These tools have been found to correlate well with physician global assessment and composite measures of disease activity [27].

A recent EULAR taskforce developed the Psoriatic Arthritis Impact of Disease () questionnaire, the first validated PRO measurement tool validated for use in PsA, which is user-friendly for both patients and physicians [28]. It encompasses 12 domains, which incorporate a wider biopsychosocial approach to psoriatic disease, such as pain, fatigue, social participation and physical functioning. Each domain is addressed through a single question, and a numerical Likert scale of 1–10 is applied to each response. The value for each domain is weighted differently, with pain rated as the highest, to give an overall measure of disease impact. Two versions of the have been developed: the 9-item questionnaire for clinical trials and the 12-item questionnaire for routine clinical practice. The cut-off value for a patient-acceptable symptom state is $\leqslant 4$ [28].

The questionnaire was validated in an international cross-sectional and longitudinal study of >470 patients, and was found to have high reliability, generalizability and strong correlation with patient global assessment [28]. In a cohort of 129 patients with PsA, when the relationship between the individual components of the questionnaire was compared with established PRO tools in those respective domains, there was a strong correlation between the two [29]. While this supports the strength of the conventional PROs in terms of capturing patient concerns, the strong correlation of the across a range of established PROs could eliminate the need for multiple questionnaires, thereby reducing questionnaire burden for patients and improving feasibility in both clinical and research settings [30].

While the has been demonstrated to be sensitive to change [28, 29], independent cohorts and interventional clinical trials are further needed to validate it as an outcome measure. A recent OMERACT group endorsed the for inclusion in future PsA clinical trials [31], and a number of trial protocols have been published with response as a listed secondary outcome [32–34].

Assessment of clinical outcomes that are meaningful to patients and that can accurately and objectively measure treatment responses are of key importance in clinical research trials. Despite inclusion of PROs within the core outcomes measurement in RCTs in rheumatology, there are still some inherent limitations in self-reported measures and wider assessment of disease impact as a primary outcome. Advances in mobile technologies, such as wearables and other remote sensor devices, as well as the widespread presence of smartphones, provides an exciting opportunity to collect far more objective clinical data on trial participants in real-time, allowing more nuanced interpretation of different treatment responses in different patients.

Future directions

There has been limited implementation of mobile technologies in PsA clinical trials; nonetheless, if we examine the technology through the wider lens of rheumatology as a whole, it is evident to see the face validity these approaches hold for PsA. This review will now explore these tools and examine their applicability in the assessment of PsA.

Electronic PROs

People living with PsA experience continuous daily symptoms that fluctuate over short periods. Clinical decisions made at intermittent consultations are based on history taking and, increasingly, on use of patient-reported tools. These are subject to pitfalls such as difficulties describing the course of fluctuating symptoms and recall bias as patients try to summarize the impact of an extended period into one questionnaire or conversation.

The increased availability and capabilities of smartphones has led to a surge in the number of studies and platforms used for symptom tracking in rheumatology. The REMORA app has been developed for patients with RA, whereby patients can remotely upload their symptoms onto their mobile phones. Responses are then

logged onto their electronic health records and can guide the next consultation between the patient and clinician, showing trends in symptoms over time [35]. The REMORA app also allows encryption of patient identifiable information so that it can be safely and ethically used for data analysis in a research setting. It is thought that the temporally rich dataset will allow for insights and understanding into the onset of flares and fluctuations in symptoms, not previously establishable from conventional approaches. Further to this application, a patient-based approach has led to the development of ArthritisPower, a free-to-use app from the patient support group, CreakyJoints. ArthritisPower is a remote symptom-tracker that allows longitudinal monitoring of the impact of arthritis on users. The domains are patient-specific and selected by each user, relevant to their disease profile, largely focusing on pain, fatigue and functioning [36]. ArthritisPower allows the mapping of trends in patient-reported symptoms over time with a view to enhancing shared decision-making between patients and their medical team.

A recent RCT comparing weekly assessment of patient-reported symptoms, either on a remote electronic platform or by standard pen-and-paper recording, found that patients in the ePRO group, demonstrated significantly increased compliance to their anti-rheumatic treatment, as well an increased self-awareness of their condition over time [37]. This was also reflected in semi-structured interviews conducted with the patients who used the REMORA app, which found high levels of satisfaction in remote monitoring and an increased awareness of their condition and capacity for self-management [38].

Although not yet employed in PsA, these findings promise exciting possibilities for the use of ePRO tools in the assessment of real-time patient-reported symptoms, potentially leading to novel endpoints in RCTs and more holistic assessment in clinical practice.

Limitations of electronic PROs

There has been much excitement surrounding the implementation of ePROs across medicine; however, there remain some challenges surrounding their usage. Despite the widespread presence of smartphones, the platforms themselves require some degree of computer literacy, and there is a risk certain patients may be excluded due to advances in technology. Patients with arthritis may also struggle with their hand function and dexterity, which may make data input difficult. To avoid unequal provision, it is imperative that these tools are designed and validated with all patient groups in mind. To enhance inclusion in clinical practice, a major challenge is the linking of patient responses with electronic health records to achieve a more seamless clinical and research workflow. In planning the implementation of PROs within the electronic health records, it is essential for decision-makers to establish goals for both local implementation and higher-level coordination, ultimately aiming for enhanced patient-centred care.

Passive monitoring

While mobile apps provide an opportunity for increased frequency of recording of patient-reported symptoms so as to encapsulate the daily fluctuation of the condition, there is potential for irregular compliance and user fatigue on the platform. The surge in the availability of wearable devices (e.g. wrist accelerometers, fitness trackers and smartwatches) has enabled the continuous, passive monitoring of real-time health status. The strength of passive monitoring is that it allows detailed and objective decoding of various domains of PsA, including sleep disturbance, physical activity, and mobility, with minimal selfor observer input. This has the potential to create distinct biosignatures that may represent different disease states.

A number of approaches have aimed to integrate subjective app-based patient-reported questionnaires with objective passive data collection, using accelerometry or geolocation. The Knee Osteoarthritis, Linking Activity and Pain Study, the first such study in the musculoskeletal sciences, is currently undergoing final analysis [39]. This study is aimed at testing the feasibility of using consumer-grade cellular smartwatches to monitor daily activity and a smartphone app to record subjective experiences of pain. This study will provide valuable information on the utility of wider-scale mobile health monitoring, both for clinical practice and research trials in musculoskeletal medicine.

A recent pilot study by Gossec and colleagues utilized a step counter to monitor daily physical activity and weekly self-report questionnaires on frequency and severity of flares in patients with RA and axial SpA, employing a machine-learning approach to demonstrate that self-reported flares correlate with a reduction in physical activity [mean sensitivity: 96% (95% confidence interval 94–97%), mean specificity: 97% (96–97%)]. Importantly, other factors related to health-related QoL (e.g. mood, illness and weather) were not collected, so this did not eliminate the possibility of confounding factors [40].

A recent Apple venture into health-care research has led to the development of ResearchKit, an open-source framework for building apps that collect concurrent physical activity metrics as well patient-reported symptoms. In the PARADE study for patients with RA, the ResearchKit was used to provide weekly questionnaires on pain, fatigue and other health status domains, combining this with an objective wrist range of motion assessment, designed using the in-built gyroscope and accelerometer of the smartphone [41]. There was an association between reduced wrist range of motion and severe self-reported pain; however, as there was no control group or baseline measure for this end point, significance could not be determined [41]. This study, although requiring further validation, opens an exciting avenue for the future assessment of PsA and other inflammatory arthritides, both in research studies and clinical practice. It is imperative that the regulation surrounding site-less telemedicine trials continues to move at the pace of the technology.

The utility of these tools to capture a wide range of health data has been identified, and the first RCT in rheumatology to use wrist-worn accelerometers to

obtain information on physical activity and sleep quality has been initiated. The ASLeap study is a phase 4 multicentre RCT aimed at measuring the clinical difference achieved through administration of either 150 mg or 300 mg of Secukinumab, a biologic therapy that inhibits IL-17A in patients with moderate to severe AS [42]. The primary outcome measure is the proportion of patients who achieve inactive disease based on the AS DAS, with secondary analyses investigating changes in physical activity and sleep quality as measures by means of wrist-worn accelerometers. Patients with AS report extensive sleep disturbance due to pain and stiffness during the night [43], and in these patients, poor-quality sleep is strongly correlated with increased pain, fatigue, lower QoL, depressed mood, higher disease activity, and reduced physical function [44]. These findings have also been demonstrated in patients with PsA [45]. Secukinumab is an approved therapy for psoriasis and PsA; therefore, the results of this study may provide some interesting insights into the applicability of these novel tools in assessing outcomes in future PsA trials.

Although the large majority of existing studies are observational, the potential for monitoring subtle responses to treatments in future interventional trials may allow for more pragmatic approaches, including shorter trials and smaller, more heterogeneous cohorts representative of clinical practice. Prior to establishing novel end point measurements in trials, there is a need for studies examining the baseline actigraphy data and continuous ePRO measurement in patients with PsA so as to truly understand the characteristics of this complex population.

Conclusion

It is well established that PsA is a complex disease, with a varied spectrum of clinical manifestations affecting patients' functioning and QoL. The wide range of outcome measures and tools used in clinical practice and trials to assess disease outcome reflects this complexity. It is important to understand the different outcome measures and their utility within distinct research questions, either through assessing intervention response overall or response in specific domains. In recent years, there have been extensive efforts to move towards employing measures specific to PsA, rather than using those borrowed from other rheumatological conditions, as well as valuing the patient perspective through PROs, giving a thorough appreciation of disease burden. As the landscape continues to advance, there could be new opportunities to employ novel digital approaches in the monitoring and assessment of PsA, offering even further insight into this nuanced condition.

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