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Development of an instrument for patient self-assessment in psoriatic arthritis

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Abstract

Objective: Due to the recent pandemic, in person scheduled rheumatology appointments in many countries have been reserved for urgent cases only. Here we report the development of a multidimensional, patient completed disease assessment tool for use in psoriatic arthritis (PsA).

Methods: A focus group development and education method was used, followed by a paired observation design to assess feasibility and validity. The psoriatic arthritis disease activity score (PASDAS) was used as the basis for the clinical assessments but elements of this tool were modified during the focus group sessions.

Results: A preliminary tool assessed tender and swollen joint counts, enthesitis, dactylitis, area of skin involved by psoriasis, and scores for global disease activity, fatigue and spinal pain. In parallel assessments good agreement was found between subject and health professional assessors, though overall disease activity was low.

Conclusions: A self-assessment tool for disease activity in psoriatic arthritis has been developed in conjunction with patients demonstrating generally good agreement between patients and health professionals but more validation work is needed before it can be recommended for clinical practice.

Introduction

Psoriatic arthritis (PsA) is an inflammatory arthritis closely associated with psoriasis. PsA is a complex heterogeneous disorder with clinical manifestations in multiple areas, including joints, entheses, soft-tissues and tendons, spine, skin and nails. The assessment of disease activity requires the evaluation of each of these domains. Multiple composite measures of this complex disease are currently available but, for clinical trials, GRAPPA recently voted to use the psoriatic arthritis disease activity score (PASDAS) as the preferred disease activity measure (1).

Although PsA is a chronic progressive condition, its course may be erratic, with repeated flare-ups and remissions. Flares are an important attribute of disease activity, and assessment of flares is useful in clinical practice and clinical trials to better understand disease status and treatment efficacy. A flare may occur in the period between routine clinic appointments. Rheumatology services often offer telephone advice and unscheduled clinic appointments to manage these flares. Patient self-assessment facilitates patient self-monitoring of disease activity and allows for active participation in self-management. Such practice is well established in other diseases such as diabetes, hypertension and asthma. Patients who self-monitor have been shown to have improved understanding and coping skills which can in turn improve treatment outcomes (2).

A patient driven disease activity instrument has been developed for rheumatoid arthritis (RA) and has demonstrated, with little training, an acceptable level of agreement with clinical assessment (3, 4). A valid and reliable patient completed PsA flare instrument has also been developed but does not include important components for the patient self-assessment of joint, skin, dactylitis and enthesitis (5). A patient self-assessment tool closely aligned to an existing composite disease activity index, the psoriatic arthritis disease activity

index (PASDAS(6)), would be of value for remote assessment. This study reports on the development of a patient self-completed instrument to assess PsA disease activity.

Materials and Methods

This study was carried out at Bradford Teaching Hospitals NHS Trust between 2016 and 2018. Ethical Permission was obtained from London South East Research Ethics Committee (REC reference 18/LO/0889). Written, informed consent was obtained from all participants. Patients 18 years and older with a consultant confirmed diagnosis of PsA attending routine clinical appointments were invited to participate in either of the focus groups, and a subsequent, different, cohort of patients were invited to take part in the parallel assessments. Patients with other inflammatory arthropathies such as rheumatoid arthritis, or with co-existing chronic pain conditions such as fibromyalgia, were excluded, as well as those who could not read or write English and did not have a family member who could translate for them.

Three cohorts of PsA patients assisted in the development and testing of a patient-based disease assessment instrument based upon a subset of the components of PASDAS (patient global, tender and swollen joint count, dactylitis and enthesitis), and an assessment of skin, spinal pain and fatigue:

Focus group 1. Development & Education

The first focus group, the development and education group (n=9), was led by an attending rheumatologist (FM). The education session reviewed the definition and management of PsA and introduced participants to the clinical components of the PASDAS (tender and swollen joint counts, enthesitis, and dactylitis). The assessment of each component was described in detail. Participants were also shown how to assess body surface area of skin affected by psoriasis, and how to score their global disease activity, fatigue, and spinal pain.

A discussion session followed, and participants were then asked to complete a short questionnaire, using 10 point Likert scales, providing feedback on disease self-assessment and their opinion on the individual domains of the disease and the likely ease of assessing themselves. There was also a comments section to capture issues that might have been missed. These processes resulted in a first draft version of a self-assessment tool.

Focus group 2. Face validity

The second focus group (n=8) was tasked with testing the validity of the first draft self-assessment instrument. The instrument was first demonstrated by the attending clinician (FM) who performed an assessment on a volunteer, demonstrating how each component could be assessed. Participants provided verbal and written feedback as to the relevance and the practicality of the components of the draft tool developed above. Participant feedback was used to modify the draft instrument further, into a second draft self-assessment instrument.

Parallel assessment

A third group (n=14) tested the instrument developed above by completing their own self-assessment of the clinical components, followed by a clinician assessment of the same components (clinicians FM, BE and PSH performed the assessments, but only one clinician per patient). No training was given to the patients prior to their completion of the instrument. The health professional was unaware of the patient scores when they performed their assessment. Agreement between assessments was compared for individual clinical components and for an aggregate clinical score (see below). As a result of this exercise some slight adjustments were made to the wording of the instrument resulting in a final version of the self-assessment tool (see on-line supplementary material).

For numerical comparison between self-completed and health professional completed assessments, the individual clinical components (thus excluding for this analysis the visual analogue scales for global disease, fatigue and spine pain) were simply added together: 68 tender, and 66 swollen joint count, the 6 sites specified by the Leeds Enthesitis Index, any tender dactylitic digits in hands and feet, and the body surface area using their own palm print as approximating to 1% of their skin surface.

Statistical Methods

As both self-assessment and clinician assessment scores were not normally distributed values were expressed as medians and range. Comparison of scores were also made using Bland-Altmann plots.

Results

Of the 31 participants 14 were male, 17 were female. 23 were white British, 2 Asian British, (6 not stated). Mean age was 54.7y (sd 2.0y), mean duration of disease 7.9y (sd 1.8y).

Focus group 1

Following an introduction to PsA and the PASDAS by the physician (FM), an open group forum discussed a proposed self-assessment tool. Subjects reported that the reduced items of the PASDAS seemed easy to understand and subjects felt confident to self-assess. Subjects thought it would be easy to self-assess joints and psoriasis as body surface area, specifically, and easy to score their global disease activity. Most participants thought that they would find it easy to self-assess their dactylitis and enthesitis. The following scores on the 10-point Likert scales were obtained on the individual items (higher scores indicate positive opinion):

- Ease of use. Range 7.5 – 10.0. Mean 9.1
- Confident in self-assessment using these outcomes. Range 7.0 – 10.0. Mean 9.0

- Accuracy of items in capturing disease activity. Range 5.0 – 10.0. Mean 7.25
- Ability to carry out:
    - Joint score. Range 5.5 – 10.0. Mean 8.7
    - Enthesitis score. Range 5.0 – 9.0. Mean 7.2
    - Dactylitis score. Range 5.0 – 10.0. Mean 7.6
    - Body surface area involved with psoriasis. Range 7.0 – 10.0. Mean 8.8
    - Global assessment of disease activity. Range 7.0 – 10.0. Mean 8.9

Five subjects commented that the assessments seemed simple and easy. Three participants thought that an App could be developed for the assessments and instrument scoring. As a result of feedback during the open discussion, the instructions were modified to clarify the recording of dactylitis and swollen and tender joints, and changes were made to the layout of the dactylitis items to ease scoring. The wording of the body surface area instructions was also modified for clarification.

Focus group 2

Subjects were given the chance to do self-assessments with supervision from the attending health professionals. Open feedback was obtained, though not formally assessed, and the instrument was further modified with further clarification of instructions for completing the dactylitis and body surface area sections.

Parallel assessments

The results of the parallel assessments for the tender and swollen joint counts, enthesitis and dactylitis counts, body surface area involved with psoriasis, and the added total of these scores are presented in Table 1. Generally, scores were low for all assessments, reflected in the median scores, though one subject scored highly across all domains. Although the median difference in score was zero for all assessments there was a wide range of

differences, with patients tending to score higher than clinicians. The Bland-Altman plots (Figure) reflect these differences though most of the scores are within the 95% confidence intervals for the difference – the patient with high overall scores was the exception.

Discussion

This study reports the development of a patient self- assessment instrument based on the PASDAS. Through a process of focus groups and patient feedback a patient self-assessment tool incorporating the clinical elements of the PASDAS was developed, with additional scores for patient global, spinal pain and fatigue assessment. In parallel assessments the patient completed instrument largely demonstrated good agreement with the assessment of health care professionals though, overall, patients had low disease activity.

A 'composite' score of these assessments is proposed to facilitate more effective communication between patients and clinicians. It is suggested that the scores for the 68 tender, 66 swollen, enthesitis, dactylitis and skin surface area be added to the scores for the patient global, spinal pain and fatigue (each assessed by an 11 point Likert scale) to produce a total score range of 0 to 290. This may seem a little cumbersome, but most patients will score below 100, even when their disease is active.

A patient self- completed instrument to assess PsA disease activity has the potential to provide patients with a tool to drive the management of their condition and determine when they will benefit most from clinical intervention. A shared language in the form of an inflammation score can facilitate direct communication with their clinician, which may be used to instigate timely management interventions. A self-completed PsA assessment tool has the potential to facilitate a more independent and fulfilling lifestyle for patients, as well as facilitating more robust remote disease management during the Covid-19 crisis.

A patient driven disease activity instrument has been developed for RA and has demonstrated an acceptable level of agreement with clinical assessment (4). Self-assessment facilitates patient self-monitoring of disease activity and allows for active participation in self-management such as in other chronic diseases: diabetes, hypertension and asthma. Patients self-monitoring has been shown to improve understanding and coping skills which can in turn improve treatment outcomes (2).

The inflammation characterised by a flare causes pain, swelling and disability and can lead to reduced activity and long-term joint damage. Prompt management of flares has both short and long-term benefits. The sustained suppression of inflammation is the current standard of care recommended by EULAR and is achieved through 'treat to target'; the target being remission or low disease activity in the form of reduced inflammation (7). In psoriatic arthritis inflammation presents itself in the form of tender and/or swollen joints, enthesitis, dactylitis, and worsening psoriasis. These markers are the cornerstone of conventional assessment of disease activity in psoriatic arthritis but require patient attendance at hospital and assessment by a healthcare professional. If these assessments can be reliably performed remotely, in person visits can then be targeted appropriately. Patient self-assessed tender and swollen joints have been moderately successful in rheumatoid arthritis where 28 swollen and tender joints were assessed, with and without training (3, 4). Generally, patients report higher scores than clinicians, as is also seen with the assessment of global disease activity(8). Studies in PsA have given mixed results but generally demonstrate higher joint counts in patients compared to physicians, particularly for higher joint counts (9). However, concordance between patient and physician in terms of global joint and skin disease activity scores was consistently good for the majority of encounters (10). In this study divergence between patient and clinician scores trended in

the same way, with patients scoring higher than clinicians. Overall, the differences in scores were within the 95% confidence limits, though there was a single outlier. Such discrepancies will have to be acknowledged when evaluating patient assessments. Patient under-reporting of clinical assessments seems not to be a problem, so the risk of missing active disease is minimal.

The Psoriatic Arthritis Disease Activity Score (PASDAS) was developed by GRAPPA and includes physician and patient reported measures combined into a single composite index (6). However, this comprehensive instrument is labour intensive to complete and complicated to calculate. Although recommended by GRAPPA for use in clinical trials, these aspects of the instrument make it impractical for use in a busy clinic. But the comprehensiveness of the PASDAS also provides the perfect basis for the development of an instrument that can be completed by patients at home allowing for self-monitoring of their disease status.

There are several limitations to this study. The initial validation of the instrument performed herein is very preliminary. Most of the patients in the parallel assessment had low disease activity, and the one patient with more active disease demonstrated more discordance in scores – this may just reflect that individual patient but may also reflect problems with self-assessment when the disease is more active. Further work, with a larger cohort of patients, is likely to provide a wider range of scores to include more severe grades of disease activity. It would also be useful to gauge the presence of co-morbidities, such as fibromyalgia, which might influence the self-assessment scores. A parallel, longitudinal assessment, with clinician scoring of the complete PASDAS, and the recording of co-morbidities, is now underway.

In conclusion, a self-assessment tool for disease activity in psoriatic arthritis has been developed in conjunction with patients. Initial validation work has demonstrated generally good agreement between patients and health professionals. Further evaluation is now warranted.

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