Psoriatic arthritis

Original research

Patient’s experience of psoriatic arthritis: a conceptual model based on qualitative interviews

Alexis Ogdie,1 Kaleb Michaud,2,3 Mirosława Nowak,4 Rachel Bruce,5 Sarah Cantor,5 Carlijn Hintzen,6 Philip J Mease7

ABSTRACT

Introduction Psoriatic arthritis (PsA) is a heterogeneous chronic inflammatory musculoskeletal disorder that manifests as peripheral arthritis, dactylitis, enthesisitis and spondylitis. PsA results in significant burden that impacts quality of life of patients. We examined the signs, symptoms and impacts reported by patients with PsA, to characterise the patient experience of PsA and develop a conceptual model representing this patient experience.

Methods Semi-structured interviews were conducted with patients with PsA recruited through the FORWARD databank. Spontaneous and probed signs, symptoms and impacts of PsA were assessed. Patients rated the disturbance of these concepts on their lives using a scale from 0 (‘does not disturb’) to 10 (‘greatly disturbs’). Signs, symptoms and impacts reported by >80% of patients with a disturbance rating of ≥5 were defined as salient concepts. Recruitment continued until concept saturation was achieved.

Results 19 patients with PsA were interviewed. The interviews elicited 42 symptoms of which 8 had not been identified in a previous literature review encompassing 15 relevant articles. The most salient signs and symptoms elicited in the interviews were joint pain, skin symptoms, stiffness, swollen/inflamed joints and fatigue all with moderate to high disturbance ratings (range: 5.5–7.8). The most salient impacts were sleep disturbance, physical disability, effects on daily activities and feelings of frustration with also moderate to high disturbance ratings (range: 6.1–7.4).

Conclusions The interviews highlighted the adverse impact PsA has on the patient’s life and may inform on outcome variables or areas suitable to be assessed in PsA studies.

INTRODUCTION

Psoriatic arthritis (PsA) is a heterogeneous chronic inflammatory disease, with joint inflammation and destruction, enthesisitis, dactylitis and spondylitis as well as psoriasis skin and nail involvement.1 PsA is experienced in many different ways, and the burden associated with living with the disease can be substantial.2,3 The negative impact of PsA on patient’s health-related quality of life (HRQoL) and functional capacity has been reported to be worse than for patients with psoriasis alone and can increase with time.4–6

Work productivity is often affected due to pain, inability to use a joint, poor sleep and fatigue. The skin involvement of PsA, often in visible locations, can result in poor psychosocial function, embarrassment, self-consciousness and depression. Additional domains that are adversely impacted by PsA or its treatment include physical, emotional, social and functional domains. This results in patients with

Key messages

What is already known about this subject?

► Psoriatic arthritis (PsA) inflicts an important symptomatic burden on patients. Several studies have reported the patient experience of PsA and have highlighted the broad range of symptoms these patients experience, particularly when the disease progresses.

What does this study add?

► Our qualitative study characterises the patient experience and perspective of PsA.

► The findings of the semi-structured interviews, together with the patient experience reported in the literature, led to the development of a conceptual model of the signs and symptoms patients with PsA experience, as reported by the patients themselves, and the impact these symptoms have in their life.

► Our study helps to identify the appropriate tools to measure those symptoms that are meaningful and impact patients.

How might this impact on clinical practice?

► The conceptual model may assist in the selection and, if needed, the modification or development of patient-centred endpoints to be assessed in clinical practice to evaluate the benefits of new PsA-targeting therapies.
PsA experiencing varied symptoms depending on the domains involved.\(^2\)\(^3\) Managing PsA symptoms and meeting patient’s needs require symptom measures that are valid and reliable. As highlighted by the Outcome Measures in Rheumatology 2016 (OMERACT 2016),\(^6\) there is a need to better understand the symptoms and their impacts that present the greatest burden to PsA patients. This would enable to identify patient-reported outcome (PRO) tools to adequately capture these concepts.\(^6\)

The objective of this study was to better characterise the patient experience of PsA and to develop a conceptual model representing the key symptoms and impacts of PsA. Additionally, we aimed to better understand the relative importance or level of disturbance of key symptoms. This work may help inform outcome measures to be followed in clinical practice and/or randomised controlled trials (RCTs) and longitudinal observational studies.

**PATIENTS AND METHODS**

**Literature review**

A targeted literature review search was undertaken in September 2018 using MEDLINE (PubMed) and Google/Google Scholar to identify literature describing concepts (signs, symptoms and impacts) related to the patient experience of PsA. The overall search strategy consisted of terms related to the disease (‘PsA’, ‘Psoriatic arthritis’ and the MeSH term ‘Psoriatic arthritis’), outcomes (‘Signs’, ‘Symptoms’, ‘Clinical manifestations’, ‘Patient Reported Outcomes’ and ‘Patient Experience’) and study design (‘Focus Group’ and ‘Patient Interview’).

Those studies providing signs, symptoms or impacts reported by patients with PsA were eligible for detailed review, and literature reporting direct patient perspectives (eg, qualitative patient interview studies or focus groups) were prioritised. However, those studies focusing on total scores of PRO instruments and not providing details on individual domains or items were excluded. Similarly, those studies focusing on a single symptom or therapy were also excluded. All titles and abstracts were screened by an experienced researcher with relevance of the selected publications confirmed by a second researcher. Abstraction was also conducted by one experienced researcher.

The literature review findings were used to construct a preliminary conceptual model of the signs, symptoms and impact of PsA. This model was tested in the patient interviews and subsequently refined based on the findings of the qualitative research.

**Patient interviews**

Semi-structured patient interviews with 19 patients were conducted to characterise the patient experience of PsA. The study was conducted in accordance with the Declaration of Helsinki and the regulations of the US Food and Drug Administration. The study and all interview materials received independent review board approval.

Participants were recruited through FORWARD, the National Databank for Rheumatic Diseases.\(^7\) To participate in the interview, participants had to meet the following predefined selection criteria: confirmed diagnosis of PsA by a rheumatologist and/or other specialist/physician who could confirm primary diagnosis; currently experiencing active symptoms of PsA; aged ≥18 years; willing, able and legally and mentally capable to provide informed consent to research; able to communicate proficiently in English; able to participate in a 75–90 min interview; reside in any state in Continental USA and with access to the internet and a telephone line. Patients could not meet any of the following exclusion criteria: currently participating in a clinical trial related to PsA; not currently experiencing any symptoms of PsA; diagnosis of fibromyalgia, inflammatory bowel disease, rheumatoid arthritis, uveitis, class III or IV congestive heart failure by New York Heart Association criteria and/or any other condition which in the opinion of the investigator would render the patient unsuitable for inclusion in the study; a mental disability or significant mental illness; legal incapacity or limited legal capacity or any other lack of fitness, which, in the opinion of the screener, would have precluded the participant’s participation in the study. Recruitment of patients for the interviews was conducted in two phases. In the first phase, treating physicians selected those patients who met the selection criteria. In the second phase, screeners contacted patients and confirmed willingness of patients to participate in the study and their eligibility for the interviews. No participant was excluded because of the screener opinion.

Informed consent was obtained via an online form completed by patients before the interview, and then confirmed at the start of the interview by the moderator. The interviews were conducted by telephone and lasted approximately 75–90 min each. Patients were offered US$125 for their participation. The interviews were structured into two parts: concept elicitation and cognitive debriefing. Only the findings of the concept elicitation part of the interviews are reported here. A semi-structured interview guide was used by the interviewers to ensure consistency in interview content. The concept elicitation part of the interview was structured into five sections (online supplemental table S1). The first section focused on the demographics of the patient, disease characteristics included in the previous and current treatments, and finally characteristics of the treating physicians. The second section was related to the symptoms the patient experienced. Patients were asked to describe any symptoms that they were experiencing or had experienced in the past (any time since diagnosis of PsA) related to PsA or its treatment. These mentions were coded as ‘spontaneous’. In the third section of the interview, the moderator went through the discussion guide and probed the patient on symptoms not mentioned yet by the patient but identified either in the literature review or during prior...
interviews with patients in the study. Any of these additional symptoms that the patient then reported were noted as ‘probed’. Given the importance of fatigue in PsA,6 patients reporting fatigue were probed to describe the experience in their own words, and descriptors were recorded. Symptoms were additionally classified as disease-related symptoms or treatment-related side effects. Interviewers probed patients on whether a symptom was experienced before, during or after treatment. If patients were able to attribute the symptom to a treatment, the symptom was coded as a side effect. Alternatively, if patients attributed the symptom to their PsA, the concept was coded as a disease symptom. Some concepts were described as disease-related by certain patients and as side effects by others. These symptoms were analysed separately and coded accordingly. The fourth and fifth sections of the interview were similar to second and third ones, but instead of symptoms, they referred to impacts of PsA. For each concept identified (in sections 2–5), patients were asked to rate the disturbance of the symptom or impact on their life using a scale from 0 (‘does not disturb’) to 10 (‘greatly disturbs’). Patients were asked, ‘On a scale of 0–10, where 0 means that this symptom/impact does not disturb your life at all and a 10 means that this symptom greatly disturbs your life, how much does this symptom disturb your life?’. If the word ‘disturb’ was unclear to the participant, the moderator used the terminology ‘negatively impact’ instead.

There are no suitable methods for power calculation in qualitative interview studies. Saturation of concepts was assessed throughout the study to ensure adequate sample size. ‘Saturation’ is defined as the point at which additional patient interviews do not contribute to unique concepts or new information.8 The concept elicitation interviews were split into four ‘waves’ or sets of interviews to assess concept saturation. The number of new concepts appearing in each wave was used to assess saturation. The sample size was determined as 20 subjects in the study protocol. However, if saturation was reached prior to the recruitment of 20 subjects, the protocol specified that recruitment would be ceased. The protocol also contemplated to increase the sample size if saturation was not achieved with 20 subjects.

Data analysis
All interviews were audio-recorded, transcribed verbatim and subject to thematic analysis facilitated by ATLAS.ti v8.3 qualitative data analysis software. Prior to initiating the interviews, a preliminary codebook that captured all symptoms and impacts identified in the preliminary conceptual model was developed, then refined after all patient interviews were completed. Each transcript was read and coded by two experienced researchers (CH and SC). The inter-coder agreement for the first four transcripts was analysed and was good (predefined as Krippendorff’s C-Alpha binary >0.7). Therefore, the remaining transcripts were coded by a single person (CH). After coding was completed, data from ATLAS.ti were exported to Excel for analysis. Very few changes had to be applied to the preliminary codebook after the patient interviews. Changes consisted in addition to those concepts elicited during the interviews that had not been identified in the literature review.

Patients were asked to rate the level of disturbance of the elicited concepts. When patients stated a range (eg, ‘a rating of 6 or 7’), the highest disturbance rating mentioned was coded for the purposes of analysis (ie, ‘6 or 7’ was considered a 7). Some patients reported disturbance ratings for multiple time periods, particularly if they no longer experienced a symptom post-treatment (eg, a patient may have reported that joint pain scored a 9 pretreatment, but that the symptom had resolved and the rating at the time of interview was 2). In such cases, the highest number was considered for the analysis to best capture the worst extent of symptom and impact disturbance.

The most salient signs, symptoms and impacts of PsA were identified to inform the conceptual model. In the model, signs and symptoms are presented together. Salient concepts were defined posthoc as those for which at least 80% of patients mentioned the concept and the average disturbance rating was higher than 5.0. This threshold identified the five symptoms and five impacts more commonly reported and considered most burdensome by patients.

RESULTS
Literature review and development of the preliminary conceptual model
The targeted literature review yielded 15 articles of which 6 related to patient interviews, 4 to focus groups, 2 retrospective studies, 1 analysis of patient perspectives, 1 cross-sectional study and 1 instrument development (the list of studies included and the PRISMA flow are provided in online supplemental figure S1). The signs and symptoms most frequently reported in the reviewed articles (online supplemental table S2) were pain (skin, joint, muscle, spine; mentioned in 14 of the 15 articles), fatigue (12 articles), skin symptoms (itching, red, scaly, etc; 9 articles), stiffness (7 articles) and swollen or inflamed joints (7 articles). The impacts most commonly reported were physical disability, social participation, sleep disturbance and emotional impact each mentioned in 10 articles (online supplemental table S3).

An additional analysis of signs, symptoms and impacts was conducted including only those studies that collected or analysed patient narratives, or studies that identified symptoms and impacts important to patients with PsA (list provided in the online supplemental material). Studies using questionnaires or ranking scales, or lacking detail on concepts important to patients or which focused exclusively on impacts were excluded. This excluded 9 of the 15 articles. The new analysis continued to identify

pain, fatigue, skin symptoms and stiffness as the most frequently reported symptoms in PsA. In contrast, anxiety, social participation and sleep disturbance became the most frequently reported impacts of PsA. A preliminary conceptual model (online supplemental figure S2) based on the targeted literature review was developed and tested during the concept elicitation interviews. This model was refined after the patient interviews.

Concept elicitation interviews

In total, 19 patients with PsA were interviewed. These patients were representative of a wide range of educational, geographic and treatment backgrounds; however, all patients were Caucasian (table 1). Overall, 42 symptoms were mentioned during the interviews. Of these, 76% (n=32) were mentioned in the first wave of interviews, 24% (n=10) in wave 2. No new concepts emerged in waves 3 and 4, demonstrating that saturation had been achieved for signs and symptoms. The most salient PsA concepts that had not been included in the original interview guide or preliminary conceptual model. These concepts included dry eyes, dry mouth and tendonitis/tendon pain, which were mentioned in the first wave of interviews, and allergic reaction (allergic reaction to medication; side effect), bone aches (influenza-like), neck pain/headache, sacroiliac joint pain and tingling limbs, all mentioned in the second wave. The symptom with the highest disturbance ratings was allergic reaction (side effect; n=2) with a rating of 10.

Patients used different descriptors to refer to symptoms. One example was skin symptoms, which patients often described them as itching, flaking or feeling hot. Of all symptoms, fatigue was the one with the highest number of descriptors. The most commonly used terms when referring to fatigue were ‘tired’, ‘fatigue’, ‘lack of energy’, ‘exhaustion’ and the concept of ‘mental fatigue’ (figure 2).

Overall, 16 impacts were mentioned in the interviews. Of these, 88% (n=14) appeared in the first wave of interviews, and the remaining 12% (n=2) in the second wave of interviews. No additional impacts were identified in waves 3 and 4, demonstrating that saturation had been achieved also for impacts. The most salient impacts mentioned by patients were sleep disturbance, physical disability, effects on daily activities and feelings of frustration. Average disturbance rates were moderate to high (range: 5.5–7.8; figure 1). Of the 42 signs and symptoms, muscle pain (reported by 11 patients), muscle spasms (7 patients), hair loss as side effect (6 patients), hair loss (5 patients), impaired vision (5 patients), headache (side effect; 2 patients) and increased risk of infection (2 patients) were reported only when patients were probed (online supplemental table S4). Eight of the signs and symptoms mentioned during the interviews were new concepts that had not been included in the original interview guide or preliminary conceptual model. These concepts included dry eyes, dry mouth and tendonitis/tendon pain, which were mentioned in the first wave of interviews, and allergic reaction (allergic reaction to medication; side effect), bone aches (influenza-like), neck pain/headache, sacroiliac joint pain and tingling limbs, all mentioned in the second wave. The symptom with the highest disturbance ratings was allergic reaction (side effect; n=2) with a rating of 10.

In general, would you say your health is . . .?

Excellent 1

Very good 2

Good 14

Fair 2

Poor 0

Table 1 Key demographics of PsA patient interview respondents

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Patients with PsA (N=19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>40–50 1 50–60 6 60–70 6 70+ 6</td>
</tr>
<tr>
<td>Sex</td>
<td>Male 6 Female 13</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Caucasian 19</td>
</tr>
<tr>
<td>US region</td>
<td>Midwest 7 Northeast 4 Southeast 3 Southwest 3</td>
</tr>
<tr>
<td>Education level</td>
<td>High school 1 College 7 Graduate 10</td>
</tr>
<tr>
<td>Time since diagnosis (years)</td>
<td>0–10 6 11–25 10 25+ 3</td>
</tr>
<tr>
<td>Patient response to ‘In general, would you say your health is . . .?’</td>
<td>Excellent 1 Very good 2 Good 14 Fair 2 Poor 0</td>
</tr>
</tbody>
</table>

PsA, psoriatic arthritis.
associated with their PsA and often found these types of pain to be distinct. Therefore, the initial ‘pain (skin, joint, muscle, spine)’ concept was broken down into individual categories of ‘skin pain’, ‘joint pain’, ‘muscle pain’ and ‘back pain’ in the final conceptual model. Spine pain was relisted as back pain, as this term better fits how patients described the symptom. Additionally, ‘musculoskeletal (muscle spasms, weakness, muscle stability)’ was separated into ‘muscle spasms’, ‘muscle weakness’ and ‘muscle stability’ as patients viewed these as separate concepts and used the term ‘muscle’ rather than ‘musculoskeletal’ to refer to these symptoms. Similarly, ‘paraesthesia’ was rephrased as ‘tingling limbs’. Finally, ‘sausage fingers’ was broadened to ‘sausage fingers/toes’ to capture patient descriptions of swelling in toes as well as in fingers.

No new impacts were added to the conceptual model as no novel impact was mentioned during the patient interviews. However, minor modifications were applied. In the literature review, articles frequently grouped together fear and frustration as one impact, but in our study,
frustration was experienced by a large majority of patients, all of which considered it to be separate from fear. Fear due to PsA was mentioned by fewer patients and they described it as a part of a broader emotional impact. In the final conceptual model, fear was combined into ‘emotional impact’ and frustration included as a separate concept to best reflect the patient experience.

A set of impacts were mentioned in less than 20% of literature review articles but were not described by patients during the interview study. These items remain in the final conceptual model for comprehensiveness, though no patients spontaneously mentioned them in the interviews.

DISCUSSION
We have developed a conceptual model that captures the patient experience of PsA. The model was based on the findings of an initial targeted literature review that identified a set of signs, symptoms and impacts reported by patients with PsA across several published studies. This set of concepts was tested in the concept elicitation interviews. Eight new concepts were mentioned spontaneously by patients during the interviews; all eight concepts were added to the initial model developed based on the targeted literature review.

In this study, the most bothersome aspects of PsA for patients were the effects on daily activities, sleep disturbance, physical disability and feelings of frustration. These results are consistent with the patient experience of PsA reported in the literature. Additional symptoms categorised as salient (ie, reported by >80% of patients and with a disturbance rating of >5) in the interviews (joint pain, skin symptoms, stiffness, swollen/inflamed joints and fatigue) are included in the OMERACT 2016 core domain set. Of the salient impacts (sleep disturbance, physical disability, effects on daily activities and feelings of frustration), sleep disturbance and physical disability are also part of the OMERACT 2016 core domain set while feeling of frustration is part of the emotional well-being OMERACT domain. The only impact that is not included is effects on daily activities although it is partly addressed with the independence and participation domains of the OMERACT core domain set.

In our interview, the symptoms with highest disturbance ratings tended to have low prevalence. The symptom with the greatest effects on patients’ lives, with a disturbance rating of 10, was classified as a side effect by patients: allergic reaction (to treatment for PsA; n=2). Additional symptoms with the highest negative consequences to patients’ life included bone pain (n=3), sacroiliac joint pain (n=3), dry mouth (n=2), increased risk of...
infection (side effect; n=5), increased risk of infection (n=2), tendonitis/tendon pain (n=6) and bone aches (‘influenza-like’; n=4) with average disturbance ratings between 8.0 and 9.5.

The OMERACT 2016 recommended fatigue to be moved from middle circle to the inner circle domain, that is, a domain that should be measured in all PsA RCTs and longitudinal observational studies. Similar to other diseases, in PsA, the aetiology of fatigue is multifactorial; pain can be due to the inflammation characteristic of the disease, chronic pain, reduced physical fitness, sleeping disorders, decreased HRQoL and emotional disorders. Our study highlights that the experience of fatigue clearly differs across patients. The descriptors patients used for fatigue included ‘tired’, ‘fatigue’, ‘lack of energy’, ‘exhaustion’ and the concept of ‘mental fatigue’. These concepts should be taken into account when measuring fatigue in these patients. While studies have shown that fatigue can improve with effective therapy, it has not always been consistently assessed in PsA studies. If a PRO instrument is used to assess fatigue, mapping of these concepts should be ensured to capture the full patient’s experience of this symptom.

Our study was subject to several possible limitations. All patients were recruited from the same registry (FORWARD—The National Databank for Rheumatic Diseases), which is the largest patient-reported research data bank for rheumatic disorders in the USA. Patients in the registry are invited to complete a questionnaire in a 6-month basis. Recruitment of patients exclusively from the FORWARD registry has potential selection bias for patients attuned to signs, symptoms and impact associated with PsA. In addition, it cannot be ruled out that some of the concepts elicited by these patients during the interviews may have been prompted or skewed by the regular questionnaires these patients complete for the registry.

Our study may underestimate the real burden and patient experience. Patients were asked to choose among five descriptors (excellent, very good, good, fair and poor) the one that would describe their health. The vast majority of patients considered their health as being good (n=14/19; 73.7%), very good (n=2/19; 10.5%) or excellent (n=1/19; 5.3%). No information on the type of patients with PsA had been collected. It cannot be ruled out that less severe forms of the disease may have been over-represented compared with more severe forms. The interviews were conducted with 19 subjects. Although this may be considered as a small sample size, it is aligned with qualitative research studies.

All patients had to have access to the internet and able to communicate proficiently in English. Barriers to internet access, such as socioeconomic status, age and education level, may also limit the generalisability of these findings to larger populations. All patients were Caucasian and all but one patient had complete high school, college or graduate school, potentially leading to further selection bias. In addition, we cannot exclude that some patients may have concomitant fibromyalgia or central sensitisation, which can contribute to how patients experience their disease. Fibromyalgia is a common comorbidity in patients with PsA with a prevalence of 15% to 20% in the PsA population, including in the FORWARD database. Fibromyalgia was an exclusion criteria, but if any of the participants may have had fibromyalgia, our findings are still generalisable to the PsA patient population in clinical practice.

All patients were recruited and interviewed between October and November 2018. A potential seasonal impact on patients’ responses cannot be ruled out. Seasonality has been reported for patients’ perception of symptoms in several rheumatic diseases. However, seasonality does not seem to affect the disease activity in PsA. In addition, patients were asked to detail the symptoms and impacts they had experienced in the past or were experiencing at the time of the interview thereby limiting the potential seasonality. Among the strengths of the study, the diagnosis of PsA had to be confirmed by the treating physician before patients could participate in the interview. This avoided participation of subjects without the disease. The interviews included patients with a broad range of disease history. Overall, 6 patients had been diagnosed within the previous 10 years, 10 had the disease between 11 and 25 years, and 3 for more than 25 years.

Our data provide valuable insight into patients’ experiences of PsA. This study highlights those symptoms and impacts that are most commonly experienced by patients and also those that are perceived as the most disturbing ones. Conceptual models that capture the patient’s perspective of their disease have been developed in the setting of rheumatoid arthritis, but this is the first attempt to develop such a model for PsA. Our work may help identify critical target areas for evaluation in clinical studies or guide investigators in selecting outcome variables or areas suitable for new therapies.

Twitter Kaleb Michaud @Dr_K.

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Contributors AO, KM, MN and PJM conceived and designed the study; RB, SC and CH conducted the literature review, and contributed to the patient interviews and data analyses; and all authors contributed in the writing of the manuscript.

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Competing interests AO has received consulting fees and/or honoraria from AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Corrona, Janssen, Lilly, Novartis, Pfizer and Takeda; grants from Novartis and Pfizer to the trustees of University of Pennsylvania and royalties to husband from Novartis. MN is an employee of Bristol-Myers Squibb and owns stock in Bristol-Myers Squibb. RB and SC are employees and CH a former employee of IQVIA, which received professional service fees from Bristol-Myers Squibb for conducting the qualitative research study. PJM has received research grants or served as a consultant or speaker for AbbVie, Amgen, Bristol-Myers Squibb, Boehringer Ingelheim, Celgene, Eli Lilly, Galapagos, Genentech, Gilead, Janssen Scientific Affairs, Novartis, Pfizer, Sun and UCB.

Patient consent for publication Not required.

Ethics approval The study was approved by the New England IRB.

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