A multicenter, non-interventional study to evaluate patient-reported experiences of living with psoriasis

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Abstract

Background: Moderate to severe plaque psoriasis (with or without psoriatic arthritis) places significant burden on patients’ lives. Objective: Explore and document patients’ experiences of living with psoriasis, including symptoms, treatments, impact on daily lives and patient-reported functioning. Methods: In a US-based, non-interventional study, narrative interviews were conducted at baseline and again within 16 weeks. In interviews, patients with moderate to severe psoriasis indicated symptoms, ranked symptoms according to level of bother and indicated areas of their lives affected by psoriasis. Transcripts of interviews were coded for themes. Measurements of psoriasis severity including BSA, PGA and PASI were recorded. Results: Symptoms reported most frequently included flaking/scaling (non-scalp areas), itching/scratching and rash, while the most bothersome symptoms were itching/scratching, flaking/scaling (non-scalp areas) and skin pain. Frequently reported impact areas were social and emotional. Conclusion: Broad-reaching interviews with patients with psoriasis show that these patients suffer in many aspects of their lives and in ways not indicated by typical psoriasis severity measures. Patients with psoriatic arthritis reported symptoms and disease-related complications at higher rates than those without arthritis. Physicians’ explorations of the effect of psoriasis on patients’ lifetimes could aid in managing these patients.

Introduction

Studies of quality of life (QoL) among patients with psoriasis suggest that the disease and its required care and treatment are associated with substantial social, physical, emotional and other burdens on patients’ lives (1–5). Many patients report difficulties sleeping or performing everyday activities (6) and have symptoms that negatively affect emotional state, self-perception and/or sexual functioning (7,8). Feelings of shame, anger, worry and annoyance are common (7,9). Such burdens tend to increase with increasing severity of disease (1,9), and symptoms are often exacerbated by external factors (e.g. environmental stressors) or health behaviors (e.g. smoking) that can, in turn, alter patients’ functioning and decisions, such as in physical activity, clothing choices and participation in relationships and social opportunities (7). Moreover, previous research has shown that these disease burdens, as well as the stigmatization associated with psoriasis, can have a cumulative effect over the course of a patient’s lifetime (10).

Various assessment tools are available to evaluate QoL in patients with psoriasis (5,9,11,12). Such tools may account for only a limited scope of symptoms (7); others focus on aspects of daily life and functioning but less so on symptoms (9,12) or their severity (13). Many do not account for psoriatic arthritis (PsA)-related symptoms. There are also, currently, few well-designed qualitative studies that employ a semi-structured interview format to elicit patients’ experiences of living with psoriasis. In this study, we systematically gathered and analyzed these patient-reported experiences. We focused on patients’ reports of symptoms, experiences with psoriasis treatments and the impact of psoriasis and/or PsA on patients’ daily lives and functioning to understand and increase awareness of the burden that psoriasis can have on patients’ lives.

Methods

Patients

This was a US-based, multicenter, non-interventional, narrative study to evaluate patient-reported experiences of living with moderate to severe plaque psoriasis, with or without PsA. All investigators (see Appendix) were dermatologists who treat patients with moderate to severe plaque psoriasis. Eligible patients included men and women who were aged ≥18 years, could read and speak English, were residing in the US, had a...
plaque psoriasis diagnosis for ≥6 months, were current candidates for systemic therapy or phototherapy, had a peak current or historical Physician’s Global Assessment (PGA) score of ≥3 (range: 0, cleared psoriasis, to 5, severe psoriasis) and were willing to give informed consent to provide an audio-recorded narrative describing their disease experiences and allow clinical photographs to be taken twice during the 16-week study. Patients with guttate, pustular or erythrodermic psoriasis were excluded. The protocol was approved by a central Institutional Review Board (IRB) and by local IRBs at sites where required. All research was conducted according to the Declaration of Helsinki principles. This study was registered at www.clinicaltrials.gov (NCT01555606) and is not part of any other study. The study ran for 13 months from the enrollment of the first patient to the last patient’s final visit.

Of 108 patients screened from eight sites, seven did not qualify due to screening failure; thus, 101 patients were enrolled (Figure 1), 35 of whom had concomitant PsA. Eleven patients discontinued early. Ninety patients completed two visits (baseline and an interval or 16-week visit). Of these, only 10 patients had interval visits; therefore, data from interval and 16-week follow-up visits were combined and analyzed together.

**Narrative interviews**

Semi-structured narrative interviews based on a discussion guide were conducted with each patient by site-based interviewers who were specifically trained (i.e. in-person and via web conference and training video) on the study protocol and narrative interview techniques. Each patient completed a baseline (week 0) interview describing his/her experience of living with plaque psoriasis (and PsA, if applicable). Baseline interviews included a card-sorting exercise in which each patient listed his/her past and current symptoms, followed by a ranking according to level of bother (“1” indicating most bothersome). A second assessment at week 16 was obtained for further details. Per protocol, patients with a clinically significant change in disease status could, instead, complete their second site-based assessment at an interval visit between weeks 0 and 16, with a final assessment for adverse events (AEs) via telephone at week 16.

**Data collection**

Site-based interviews were audio-recorded and subsequently transcribed by RTI Health Solutions (RTI-HS; Research Triangle Park, NC) in a standardized, quality control-checked manner. Specifically, interviews were transcribed by a qualified medical transcriptionist. A second medical transcriptionist then reviewed the draft while listening to the recorded interview, making any necessary edits or corrections. Identifiable patient data were removed from transcripts prior to release to RTI-HS. Final transcripts were provided to the authors and to RTI-HS for analysis. Clinical patient photographs and video recordings were also obtained throughout the study.

Electronic case report forms (eCRFs) were used to collect data on patient demographics, disease characteristics (i.e. body surface area [BSA], PGA and psoriasis area and severity index [PASI]), and other variables, such as prior and concomitant medications and AEs. Patient-reported symptom information was also recorded in the eCRF.

To guide a neutral, uniform and systematic process for identifying qualitative themes and subthemes in patient responses across interview transcripts, two RTI-HS coders iteratively developed a qualitative codebook from the qualitative data captured in patient interviews. Dominant trends were identified in each interview and compared across results of the other interviews to generate themes or patterns in the ways that patients described their symptoms, bother rankings and disease impact on their lives. Additional codes were created, as needed, to summarize qualitative data. Approximately 10% of transcripts were double-coded (i.e. coded by both coders) to ensure consistency in coding. Information and codes pertaining
specifically to patient interviews were entered and maintained in the qualitative analysis software ATLAS.ti version 6.2 (ATLAS.ti Scientific Software Development GmbH, Berlin, Germany).

As patients were not provided a definition of “symptoms,” many reported emotional, social, family, professional, physical, sexual or educational aspects of their lives, which we termed and coded as “impact areas.” Meanwhile, symptoms included physical manifestations of psoriasis or PsA. Symptoms and impact areas were counted only once for each patient. Patient-rated symptom bother rankings were adjusted to ensure that only symptoms – not impact areas – were reported and analyzed in terms of how bothersome they were to patients. More than one symptom or impact area was often counted for any single patient statement.

Subgroup comparisons
We looked for differences in results among various subgroups. The following subgroups were determined a priori and are reported herein: psoriasis-only versus patients who also had PsA; treatment groups, including systemic (oral and biologic)-naïve versus systemic (oral and/or biologic)-exposed and biologic-naïve versus biologic-exposed. For all analyses, as appropriate, chi-square tests were computed for the comparison of proportions, and t-tests were conducted for the comparison of means.

Results
Baseline demographics and disease characteristics
Patient demographics and disease characteristics at baseline are presented in Table 1. Significant differences in disease characteristics between psoriasis-only and PsA patients included psoriasis involvement of the trunk (30% versus 57% of patients, \(p<0.01\)), current treatment with a biologic (38% versus 60% of patients, \(p<0.05\)), biologic treatment at any time (49% versus 91%, \(p<0.001\)) and phototherapy treatment at any time (41% versus 66%, \(p<0.05\)).

Symptoms and symptom bother
Symptoms reported by at least two-thirds of patients included flaking/scaling of non-scalp areas, itching/scratching and rash (Table 2). Other symptoms reported by more than half the patients were flaking/scaling of the scalp area, skin pain, bleeding and redness.
More than half the patients ranked itching/scratching and flaking/scaling of non-scalp areas in their top three most bothersome symptoms, and one-third of patients reported skin pain among their most bothersome. Other symptoms frequently ranked among the most bothersome included burning, redness and bleeding (Table 3 and Figure 2). Compared with psoriasis-only patients, patients with PsA were more likely to report skin pain and joint pain among their most bothersome symptoms.

This observational study was non-interventional; therefore, any administration of therapies to patients by study investigators was part of usual care. The study was not designed for the purpose of eliciting safety data; however, sites were trained to capture and report AEs spontaneously reported by patients. Six AEs were identified either through investigator reports or through review of interview transcripts. These AEs were: exacerbation of psoriasis (1), decrease in appetite (1), swollen joints (1), histoplasmosis (1), breakout of psoriasis (1) and joint pain (1).

Impact areas

Of seven impact areas (Table 4), emotional and social impacts were the most frequently reported (98 and 95%, respectively, for all patients; Figure 3). Social impacts often included avoidance of, or changes in, activities (e.g. sports, vacations) or relationships or the avoidance of strangers, of meeting new people or of all social interactions and activities. Table 5 describes some of the emotional impacts that patients reported. Feelings included anger, frustration, embarrassment, worry/stress, shame/self-consciousness, loneliness/isolation and perceptions of appearing unattractive/unappealing. Sense of self descriptors included having low self-worth/self-esteem/self-confidence and becoming shy/withdrawn/introverted. Mood descriptors included sadness/hopelessness/helplessness/depression and anxiety.

Approximately three-fourths of patients reported a family impact (Figure 3); patient narratives frequently addressed support from family or lack thereof, emotional impacts on family members and effects on family time activities. Approximately two-thirds of patients reported impacts on their professional lives. Psoriasis often affected patients’ career choices, abilities to perform work duties and work relationships and interactions, consequently resulting in emotional distress for some patients. Some patients, however, reported having supportive colleagues and work environments. About one-fifth of patients expressed an impact on sexual intimacy, including avoidance of sex or intimacy challenges in new relationships (e.g. need to explain the condition, and fear of how partner may react).
Although impact area patterns were generally similar between psoriasis-only and PsA patients, physical impact and educational impact had the largest disparities, affecting PsA more than psoriasis-only patients (Figure 3). Physical impacts included limited physical function (e.g., basic mobility, exercise), sleep problems and weight gain. Educational impacts – ranging from grade school through graduate school – included attendance (absenteeism or postponing), relationships at...
Disease course
Many patients reported psoriasis and/or PsA symptoms worsening in cold/winter weather due to staying covered up, dry air or lack of sun; fewer reported worsening in warm/summer weather (e.g. from heat or sweat). For some patients, psoriasis symptoms worsened at night or during stressful times. Other reported symptom triggers and exacerbators included non-adherence to treatment regimen, overactivity, excessive standing/walking or physical stress, physical trauma (e.g. cuts/scratches), alcohol intake, smoking, lack of movement or exercise, lack of rest and weakened immune system.

Coping
Patients reported that positive tools for coping with psoriasis included positive attitudes, supportive friends and family, educational resources in managing their disease and discussions with other patients with psoriasis. Negative mechanisms included hopelessness, disappointment, expressions of discouragement and frustration regarding the disease, its symptoms, ineffective treatments or lack of cure.

Patients reported making adjustments and modifying life decisions to lighten the disease burden. Most common were clothing/appearance adjustments, which presented their own hardships (e.g. long clothing in warm weather). Patients also avoided dark colors or thin materials to reduce visibility of flakes and plaques but noted that light colors could be ruined from bleeding. Some patients also used makeup or hairstyles specific to their psoriasis.

Receiving, accessing and perception of care and treatments
Factors attributed to easing the process of receiving care were: good insurance, good health care providers and care received and effective treatment. Factors that caused difficulty in receiving care were: financial difficulties (expensive copays, lack of insurance or difficulties obtaining insurance coverage/approvals); lack of knowledge and undervaluing of psoriasis (by physicians/insurance/society); finding effective treatments; and inconvenient treatments. Patients placed high value on health care professionals’ level of knowledge about psoriasis, current treatments and ongoing research, with primary complaints focused on lack of these or unwillingness to try new/different treatments.

Patients expressed both positive and negative aspects of psoriasis treatment. The most positive aspects pertained to symptom improvements with effective treatment. Some patients who experienced symptom improvements gained confidence, self-esteem, physical activity and/or the ability to expose their skin. Most of the negative aspects involved treatments considered messy, uncomfortable (e.g. topicals and shampoos) and/or time-consuming (e.g. phototherapy) or adverse effects or loss of efficacy over time. Treatment could also be a burden for patients due to cost, missed work and need to switch therapies if they lost efficacy. Patients also reported treatment side effects (e.g. pain, burning, bruising, fatigue, nausea, stinging, skin thinning and immune system compromise), some described as worse than the disease itself.

Changes reported at study end
Of patients who completed 16 weeks of the study, most reported some level of disease change from baseline, which may reflect normal fluctuations in disease and its treatment. Some patients attributed changes to factors such as stress, illness, weather or new treatment regimens.

Table 4. Definitions of impact areas.

| Impact area category | Description |
|----------------------|-------------|
| Emotional            | Mood, feelings, identity, confidence and self-worth |
| Social               | Friends, activities, sports and relationships |
| Family               | Activities, relationships and responsibilities |
| Professional         | Work, relationships, career choices and decisions |
| Physical             | Functioning and other physical impacts |
| Sexual               | Intimacy (emotional and physical), sex activities and interest/desire |
| Educational          | Student life, starting or continuing school and school choices |

Figure 3. Frequency of reporting by impact areas for psoriasis-only and psoriasis + psoriatic arthritis patients. Impact areas are described in Table 4. A patient was counted in an impact area if the patient made at least one statement that was coded in that category. P Values are provided for any statistically significant differences between psoriasis and psoriasis + psoriatic arthritis patients.
### Subgroup analyses

Overall, patients with PsA reported more symptoms (mean [SD]) than psoriasis-only patients (10.5 [2.3] versus 8.3 [3.0], \( p < 0.001 \)), including disease flare-ups (66% versus 39%, \( p < 0.05 \)), joint pain (83% versus 20%, \( p < 0.001 \)), joint inflammation/swelling (31% versus 6%, \( p < 0.001 \)) and joint stiffness (23% versus 2%, \( p < 0.001 \)). Patients with PsA also reported more impact areas (4.8 [1.3] versus 4.1 [1.2], \( p < 0.01 \)) compared with psoriasis-only patients.

A greater percentage of systemic-exposed patients (\( n = 81 \)) had a PsA diagnosis compared with systemic-naïve patients (\( n = 20; 42\% \text{ vs. } 5\% \), \( p < 0.01 \)). Mean (SD) numbers of reported symptoms were higher for systemic-exposed patients compared with systemic-naïve patients (9.5 [2.8] versus 7.2 [2.7], \( p < 0.01 \)), as were mean (SD) numbers of reported impacts (4.5 [1.2] versus 3.6 [1.3], \( p < 0.01 \)). Patients with or without biologic treatment were generally similar in demographic and clinical characteristics; however, biologic-exposed (\( n = 69 \)) patients were more likely to have a PsA diagnosis (48% versus 6%, \( p < 0.001 \)) and for a longer duration (mean [SD] years, 9.9 [8.0] versus 5.5 [3.5], \( p < 0.001 \)) compared with biologic-naïve (\( n = 32 \)) patients. Mean (SD) numbers of reported symptoms were also higher for biologic-exposed patients compared with biologic-naïve patients (9.8 [2.7] versus 7.5 [2.8], \( p < 0.001 \)), as were mean (SD) numbers of reported impacts (4.5 [1.2] versus 3.9 [1.3], \( p < 0.05 \)).

### Discussion

Unlike a typical QoL assessment, we allowed patients to freely describe the effects of their disease on their QoL. As a result, the interviews captured the far-reaching ways in which psoriasis and PsA affect all aspects of patients’ lives and the “control” that the disease exercises over so many of their activities. Using a uniform, structured methodology to assess the patients’ wide-ranging concerns engendered by psoriasis, we identified concepts of greatest relevance to patients, which may help in selecting or developing patient-reported outcome instruments for evaluating the disease burden and the effects of treatments in patients with psoriasis. While many of the issues raised by patients could have been anticipated, it is necessary to capture, analyze and catalog their concerns to fully understand the impact of psoriasis.

Patients’ frequently reported symptoms of itching, flaking, pain and burning may not be properly appreciated in routine clinical settings and usually are not measured in clinical trials for psoriasis [although some have been reported as similarly frequent and problematic in other qualitative studies focusing on patient perspectives (7,8,13)]. Assessment of these symptoms gives a more complete picture of the degree of suffering of a psoriasis patient than does the PASI, BSA or PGA alone. Furthermore, patients’ reported impact areas relating mainly to daily life events in the detail that we obtained cannot be extracted from routine QoL questionnaires. To truly understand the burden of psoriasis, we must delve into patients’ experiences, as we did in this study (Tables 2–5 and Supplementary Material).

Our study documented the effect that patients’ psoriasis has on their families. Psoriasis may affect family time, intimacy with family members, and may also affect financial resources based on choice of profession. It is likely, based on patients’ comments on their challenges in new relationships, that psoriasis may have altered who became their eventual spouse among married patients.

We found that patients with PsA had more difficulties than those with psoriasis-only for most symptoms and impact areas evaluated in this study. Measures that evaluate only skin involvement will not capture the impact on QoL for those patients who have arthritis (14), particularly with regard to physical functioning (15). Patients with PsA use more biologic and ultraviolet therapies than do patients with psoriasis without arthritis and described more impact of the disease on their education.

Our study results might be affected by our method of selecting the patients from psoriasis centers and which patients would agree to be interviewed; thus, our data may not be representative of all patients with moderate to severe psoriasis. Although patients in this study were not required to be receiving treatment, they did participate in practicing dermatologists’ offices; thus, our dataset likely does not adequately represent people with moderate to severe psoriasis who are not seeking established medical care.

### Table 5. Selected patient verbatim statements, classified as emotional impacts, by theme.a

| Themes/subthemes | Verbatim statements |
|------------------|---------------------|
| **Feelings**     |                     |
| Self-conscious, shamed, Embarrassed | “I am very ashamed of the look, you know, like just people looking at me.”
|                   | “The flaking causes a lot of the embarrassment. And a lot of times it’s just easier to stay home than to go out.”
|                   | “You feel like you’re a leper. No one wants to get next to you. No one wants to touch you.”
|                   | “I guess the things that go hand-in-hand is ugliness, the confidence killer of it, the stares, and other people’s questions.”
|                   | “That’s all I’ve ever felt since I got psoriasis, was frustrated. Frustrated that there wasn’t an answer, there wasn’t a solution, that no one I knew had it. No one my age had it.”
|                   | “I was always worried that they would think that what I had, that I had some kind of a rash, that I had something contagious, that it was poison ivy or something.”
|                   | “It does make me mad, the psoriasis, because why did I get it? Why did I have to have it?”
| **S sense of self** | “I think it kind of molded me into this really insecure person.”
| Low self-esteem, self-confidence, self-worth, Withdrawn, introverted, shy | “It made me self-conscious about myself. And I became shy and withdrawn. I really didn’t want to be around people. I was embarrassed because of those symptoms.”
| **Mood**          | “The depression affects my whole family, not just me. I cry a lot and my daughter sees that, I don’t like her seeing that.”
| Sad, hopeless, helpless, depressed, Anxious | “But the appearance, I couldn’t conceal that from others. And it just makes you so anxious to just hurry and get out of the line or hurry and get covered up or to get out of that situation so that you can calm down.”

aA comprehensive list of patient statements for each impact area are presented in supplementary materials.
treatments for various reasons, including those who find their QoL to be satisfactory despite their degree of psoriasis involvement. In addition, participating patients’ responses may have been subject to unanticipated and unrecognized biases introduced during the interviews.

This study recorded and analyzed patients’ life experiences with psoriasis in a way that provides a perspective of disease burden not typically obtained in clinical trials or other studies. Further, in most clinical care episodes, patients are unlikely to have the opportunity to describe the effects of their disease that we have documented (Tables 2–5). Thus, our data provide practitioners with deep insight into how patients with moderate to severe psoriasis are suffering, regardless of whether the concerns are elucidated during patient visits. The burdens in patients’ lives support the use of effective treatment; indeed, patients expressed how they value physicians who are knowledgeable about psoriasis and who will try various therapies. In summary, our findings highlight the usefulness of patient-reported outcomes – to look beyond cutaneous appearance and joint inflammation – to understand comprehensively the numerous effects of psoriasis and arthritis in order to manage appropriately patients with psoriasis.

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Declaration of interest

Mr. Schenkel and Drs. Carter and Farahi are employees of Janssen and own stock in Johnson & Johnson, of which Janssen is a subsidiary. Dr Ellis is a consultant to Johnson & Johnson and to other manufacturers of proposed or marketed therapies for psoriasis and holds a patent on the Lattice System Physician’s Global Assessment for evaluating psoriasis. Dr. Pariser is or has been an investigator for Asubio Pharmaceuticals, Inc., Dow Pharmaceutical Sciences, Inc., Eli Lilly and Company, Graceway Pharmaceuticals, Intendis, Johnson & Johnson Consumer Products, Inc., Novo Nordisk, Peplin and Proctor & Gamble Company; a consultant for Brickell Biotechnology, Genentech and Medicis; and an investigator and consultant for Abbott/Abbvie, Amgen, Astellas, Celgene, Dermira, DUSA, Galderma, Janssen, LEO Pharma, Novartis, Ortho Dermatologics, Pfizer, Inc., Photocure ASA, Stiefel and Valeant. This study was supported by Janssen Biotech, Inc.

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Appendix

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Supplementary material available online

Supplementary Information