

ORIGINAL ARTICLE

## The experience of pain and redness in patients with moderate to severe plaque psoriasis

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### Abstract

**Introduction:** The Psoriasis Symptom Inventory is a patient-reported outcome instrument that assesses severity of psoriasis signs and symptoms. In early qualitative research, patients reported pain related to psoriasis skin lesions and redness of affected areas of skin as key symptoms. **Methods:** Individual concept elicitation interviews and cognitive interviews were conducted in adults with moderate to severe plaque psoriasis. Interviews were audio-recorded and transcribed. Concepts were identified, coded and grouped by similar content using Atlas.ti software. Results were evaluated using qualitative research methods. **Results:** Of 30 patients recruited, 20 patients participated in concept elicitation interviews and 10 participated in cognitive interviews. Concept codes for skin pain and descriptions of color comprised 11% and 15%, respectively, of all symptom-related expressions. Of 90 pain-related expressions, 22 were about pain related to unconscious scratching and 68 were about pain from the psoriasis lesions. Of 199 color-related expressions, 72 were about red or reddish lesion color. Patients with darker skin tones were found to interpret redness consistently. **Discussion:** These results provide further support to content validity of pain and redness concepts in the Psoriasis Symptom Inventory. **Conclusions:** Symptoms of skin pain and redness are highly relevant to patients with psoriasis.

### Keywords

Psoriasis signs and symptoms, Psoriasis Symptom Inventory, severity

### History

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### Introduction

Patients with psoriasis experience many skin symptoms in the course of this chronic disease, including lesion pain and redness. Pain has been self-reported as a symptom in 17–83% of patients with plaque psoriasis (1–4). Skin redness is also a common symptom in patients with plaque psoriasis and has been self-reported in 71–79% of patients (3,5). Patients with psoriasis who experience pain are more likely than patients without pain to miss work (odds ratio [OR] = 1.78; 95% confidence interval [CI] = 1.30–4.10), experience reduced productivity while at work (OR = 1.53; 95% CI = 1.12–2.09) and have difficulty performing daily activities (OR = 1.53; 95% CI = 1.19–1.96) (3). Notably, pain associated with psoriasis has a severe negative effect on sleep, which profoundly affects health-related quality of life (HRQoL) (1,6,7). Less is known about the impact of skin redness on HRQoL in patients with psoriasis. Patients with psoriasis experience varying degrees of skin discoloration due to plaque lesions. Although the term “redness” is included in clinical assessments, qualitative data supporting consistency of lesion

color description are limited, especially among patients with darker skin tones.

The Psoriasis Symptom Inventory is an eight-item, patient-reported outcome (PRO) instrument of the severity of psoriasis signs and symptoms that has been shown to be reproducible and responsive to change (8–10). The eight signs and symptoms included in the Psoriasis Symptom Inventory are itch, redness, scaling, burning, stinging, cracking, flaking and pain. The Psoriasis Symptom Inventory was developed in accordance with the United States Food & Drug Administration 2009 guidance for PROs (11). The eight concepts were identified based on qualitative focus groups conducted in patients with varying levels of psoriasis severity. Input from clinical experts and a review of the literature informed the instrument development effort. This additional qualitative study used individual interviews to further evaluate the content validity of the Psoriasis Symptom Inventory, specifically around the inclusion of the concepts of pain and description of lesion color. Individual qualitative interviews provided the opportunity to gain additional insights over the initial focus groups. This study design allowed for an exploration of whether patients with darker Fitzpatrick skin types (12) interpret the “redness” of their skin lesions with consistency and also to identify the degree to which skin lesion pain is a clear and important concept experienced by patients with moderate to severe chronic plaque psoriasis. The purpose of this analysis was to better understand the relevance and consistency of the symptomatic experience of pain and redness in moderate to severe psoriasis patients and to further evaluate the content validity of the Psoriasis Symptom Inventory items addressing these two concepts.

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## Methods

### Study design

Individual qualitative interviews were conducted in patients with psoriasis across all six Fitzpatrick skin types at four US sites in Washington, Colorado, Georgia and California. Twenty concept elicitation interviews were conducted using semi-structured interview guides to identify concepts that were relevant to the patient experience, to explore variability of symptoms and to identify the language used by patients to describe their symptoms (8). Interview transcripts were coded using Atlas.ti software, and patient language was grouped by similar content or themes for evaluation.

Cognitive interviews were conducted to evaluate patient understanding of the concepts presented in the Psoriasis Symptom Inventory items (8). These interviews used a semi-structured interview guide focusing on Psoriasis Symptom Inventory items, instructions and response options. Interview transcripts were summarized by response to each question. Relevance of pain to the psoriasis patient's experience was assessed using the patients' descriptive language to identify related themes and assign codes to similar content. The resulting concept codes were evaluated for predominance (how much patients talked about each concept). Symptom severity was rated on a 0–10 numerical rating scale. Each symptom expressed was described as either being offered spontaneously or in response to follow-up probes.

### Patients

This study population included adult patients ( $\geq 18$  years of age) with moderate to severe psoriasis. Participants had Psoriasis Area and Severity Index (PASI) scores  $\geq 12$ , psoriasis-affected body surface area (BSA)  $\geq 10\%$  and Physician's Global Assessment (PGA) score  $\geq 3$ . Participants were either untreated or on topical therapies, and their symptoms were relatively stable.

Patients were recruited across the spectrum of skin types based on Fitzpatrick classification (12). Fitzpatrick skin types are categorized as: Type 1 (red hair with fair skin and highly sensitive to sun exposure), Type 2 (fair hair with fair skin and very sensitive to sun exposure), Type 3 (pale skin with darker hair and sun sensitive but can tan), Type 4 (light brown skin with brown hair and minimally sun sensitive), Type 5 (brown skin with darker hair and sun insensitive) and Type 6 (very dark skin with black hair and sun insensitive).

## Results

### Patients

A total of 30 patients with moderate to severe psoriasis were included in this analysis, including 20 patients who participated in concept elicitation interviews and 10 patients who participated in cognitive interviews. The concept elicitation group was 90% male, 75% white, had a mean age of 52 years, mean PASI score of

18.4 (standard deviation [SD] 5.0) and mean psoriasis-affected BSA of 25.5% (SD 13.7). Eleven patients (55%) had a PGA score of 3 (moderate disease), eight patients (40%) had a PGA score of 4 (severe disease) and one patient (5%) had a PGA score of 5 (very severe disease). The cognitive interview group was 73% male, 67% white, had a mean age of 52 years, mean PASI score of 16.3 (SD 7.6) and mean psoriasis-affected BSA of 18.6% (SD 7.6). Six patients (60%) had a PGA score of 3 and four patients (40%) had a PGA score of 4.

### Qualitative assessment of pain

#### Frequency of pain-related expressions

Pain was the fourth most predominantly discussed symptom by patients in the concept elicitation interviews, comprising 11.4% of all symptom expressions. Pain was reported spontaneously by 11 of the 20 patients (55%) and by another five patients (25%) in response to follow-up probes. A total of 90 pain-related expressions were coded from the 20 qualitative interviews, and these coded expressions were grouped into categories by similar content (Table 1). While 22 of these expressions (contributed by 9 of the 20 patients interviewed) were about pain caused by unconscious scratching, and 13 patients contributed another 68 expressions of pain sensations that related directly to their psoriasis skin lesions. Examples of patient quotes about general and specific pain-related expressions are listed in Table 2.

#### Skin pain vs joint pain

The Psoriasis Symptom Inventory asks patients about the severity of the pain in their skin lesions. Many patients with psoriasis also have psoriatic arthritis, which causes joint pain. Therefore, patients were also asked about joint pain in the concept elicitation interviews in order to assess any overlap in pain reporting. Examples of patient language around joint pain included, "Just like arthritis," "I start getting a pain in a joint," "Like your fingers are broken or something," "You feel the pain inside of your bones" and "Typical finger and toe psoriatic arthritis discomfort." However, patient expressions of pain coming from their skin lesions included examples such as: "At the surface. Dull (pain), at times, it can be sharp. Sharp (pain) in specific areas," "It is painful to touch" and "When I push it, I get that . . . Yeah. Skin pain." These differences in language suggest that patients with comorbid psoriatic arthritis are able to distinguish between pain from psoriatic lesions and pain from psoriatic joints and reflect their responses appropriately for skin lesion pain on the Psoriasis Symptom Inventory.

#### Severity and difficulty ratings

The 11 patients expressing pain concepts rated the severity of their skin pain at a mean rating of 6.2 (SD: 2.9) on a standard 10-point numeric response scale (NRS). The median rating was 6

Table 1. Pain-related expression frequency.

	Number of patient language expressions within concept	% of total expressions (N = 792)	Number of transcripts contributing to concept expression	% of transcripts contributing (N = 20)
Skin pain	90	11.4%		
General pain descriptions	41	5.2%	13	65.0%
Pain from scratching	22	2.8%	9	45.0%
Dull pain/ache/sore	5	0.6%	4	20.0%
Irritation	6	0.8%	4	20.0%
Stabbing/sharp pain	6	0.8%	4	20.0%
Other descriptions of pain	10	1.3%	6	30.0%

Table 2. Examples of patient quotes about psoriasis skin pain.

**What is this sensation like for you? Can you describe how it feels?**

## General skin pain

- It can be painful just like an open sore.
- I can barely graze it, it bursts, then the skin is tight red and it is hurting.
- The cracks are open scars and it's very painful because dry.

## Pain from scratching

- I try to avoid scratching, but notice when I wake up in the morning, I have been scratching. It starts the irritation, the burning type feeling.
- Maybe some aching because of the scratching.

## Dull pain/ache/sore

- All this was sore, under the fingernails.
- I want to say a dreary, like a steady pain.
- Sore lesions.

## Irritation

- One of the patches or several patches will be worse than the other. You get really bad and irritating.
- For a while after getting out of the shower, it's pretty irritated and itchy.
- The irritation came right away, when I first broke out.

## Stabbing/sharp pain

- Sensation is more stabbing, I mean it's equivalent to a friction burn.
- It is sharp when you lean on something. You are like "oh that hurts so bad."
- You can make it a sharp pain, depending on what you are doing.

## Other descriptions of pain

- It is like a sunburn, a bad sunburn, you know it's tender.
- If you touch it [plaque], it is painful.
- It is more like a throbbing with stinging.

with a range of 2–10. Fourteen of the 20 patients rated the difficulty of coping with their skin pain as 7.3 (SD 2.4) on a 10-point NRS, with a median rating of 8 and a range of 2–10.

*Pain expressions by severity*

Examples of patient quotes about the severity of their pain across patients with varying degrees of severity are listed in Table 3. Results showed that patients understood the pain item consistently and were able to utilize the response options while responding to the pain item. The response options for the pain measure were seen by patients to be appropriate for the questions, and understandable. Cognitive interviews showed that patients understood the pain item to refer to the pain in the lesion itself, and not to their joint pain.

*Qualitative assessment of redness*

A total of 119 color-related expressions were coded from the 20 concept interview transcripts. Of these, 60% of the expressions ( $N=72$ ) cited red or reddish lesion color, 12% ( $N=14$ ) cited shades of pink to red tones and 8% ( $N=10$ ) described purplish red and dark-red tones. Patients with darker skin tones (Fitzpatrick scores of 4, 5 or 6) described their lesions as red, bright red, flashy red, reddish brown, deep red and dark red. New lesions were described by patients with lighter skin tones as pink and peach or light orange, while those with darker skin tones reported only pink tones. All participants described fading lesions using red to reddish brown, moving to tan and brown skin tones once the lesion was healed. For all participants, lesion color at its worst for fully developed lesions was described as dark red, deep red, really red, blotchy red and fire engine red. Comments about lesion color across Fitzpatrick skin types are listed in Table 4.

**Discussion**

The content for the Psoriasis Symptom Inventory items on pain and redness was originally developed using qualitative interview results from patients, clinician input during the item generation process and additional input from patients during the early cognitive interview process (8). Patients with concurrent psoriatic arthritis were included in both types of qualitative interviews. Qualitative findings from the concept elicitation interviews and cognitive interviews conducted in this study regarding the presence and severity of pain provide evidence for the inclusion of pain as a key symptom concept that is relevant to patients with moderate to severe psoriasis. Furthermore, "pain" is an appropriate term for describing a sensation experienced in relation to psoriasis lesions that is not covered by other items. The results of this study showed that "pain" was conceptually different than other items such as "burning sensation" or "stinging sensation," which tend to be symptoms associated with inflammation and lesion cracking/tearing, respectively.

Redness of skin lesions was the most commonly used descriptor of discoloration in psoriasis across all Fitzpatrick skin types, even for those with darker skin tones. Results indicated that patients described their psoriasis lesions in varying hues of red when the symptoms were at their most severe. These findings lend further support to the content validity of the "pain" and "redness" items that have been included as concepts addressed by the Psoriasis Symptom Inventory.

Patient-reported measures that are currently used to assess the patient's perspectives in clinical trials include the Dermatology Life Quality Index (DLQI) (13), the Short Form-36 (SF-36) Health Survey (14), the Psoriasis Disability Index (15) and the EuroQol (16). Although these measures are effective at capturing the effect of various aspects of psoriasis on HRQoL, none specifically evaluates the severity of psoriasis-specific symptoms. The Psoriasis Disability Index is specific for psoriasis-related limitations, whereas the DLQI is more globally applicable to impacts of dermatologic diseases. The SF-36 and EuroQol are generic instruments and less sensitive to psoriasis-specific effects. The Psoriasis Symptom Inventory provides a low-burden, condition-specific means to assess the severity of psoriasis signs and symptoms as an outcome in studies of psoriasis treatment. The extensive qualitative research conducted during the early development of the measure (8), followed by the qualitative study described in this study, provides robust evidence of the content validity of the Psoriasis Symptom Inventory. As a simple, content-valid PRO measure of psoriasis signs and symptoms, the Psoriasis Symptom Inventory fills an important measurement gap within clinical trials designed to assess the efficacy of agents for the treatment of moderate to severe chronic plaque psoriasis. The rigorous instrument development process followed for the Psoriasis Symptom Inventory renders it suitable for consideration as a relevant efficacy endpoint.

The results of this analysis may be generalizable to most patients with moderate to severe psoriasis. Patients were not excluded based on comorbidities and were generally eligible to receive systemic therapies based on the severity of their disease. In addition, patients with darker skin tones (Fitzpatrick Types 4, 5 and 6) were specifically included in the study to capture the concept of redness across patients with varying skin colors.

In conclusion, concepts of pain and redness are highly relevant to patients with psoriasis, and these results provide further support for the content validity of these items in the Psoriasis Symptom Inventory. Results from concept elicitation interviews and cognitive interviews provided strong evidence in support of the wording of the redness and pain items in the Psoriasis Symptom Inventory.

Table 3. Gradient of pain expressions across response options.

Overall, during the last 24 h, how severe was the pain you felt from your skin lesions?	Mild	Moderate	Severe	Very severe
Not at all	<ul style="list-style-type: none"> <li>• I guess you wouldn't even feel it. You wouldn't even notice that you have it. You would feel good.</li> <li>• Just normal I would say. I could itch off and on, but it is still not pain.</li> <li>• Well I don't, I don't know, because, well I guess you just don't have no pain or soreness. No pain or soreness.</li> <li>• Not hurting at all. Just cool, calm, and collected.</li> <li>• To the point if I don't feel anything when I do this again. Like not too much pain. Only if I initiate the pain, like if I scratch it, then that's the pain.</li> <li>• Mild would be just your superficial if I hit it, it might be painful, but otherwise, no pain.</li> <li>• Mild? I guess you would, it would be that little bit of discomfort more than anything.</li> <li>• Stinging, I marked it mild because I haven't had a lot of stinging.</li> <li>• Mild pain would be annoying, irritating; it would be noticeable and it would definitely interfere with normal activities.</li> <li>• When you are leaning on something, that is when you feel that pain.</li> <li>• Mild is a little bit of pain, a little bit of uncomfortability, then it goes away quick.</li> </ul>	<ul style="list-style-type: none"> <li>• Moderate would be, the pain level or what it would look like.</li> <li>• But if it's moderate it's like I'm not doing anything to cause it.</li> <li>• I think it is just varying moderate would again, would be how much does it make me aware of itself during the day, so if it is on and off painful, then it would be moderate.</li> <li>• Moderate pain to me is just more about, like I said, when you itch, how it hurts. I mean there is very little cracking right now. So it's not, the cracking is not that bad right now. So it's not from the cracking the pain...</li> <li>• It is there, but it doesn't bother me much.</li> <li>• The same thing, it would just be the same as mild. It wouldn't be that uncomfortable; moderate might be a little more uncomfortable, but basically I think it wouldn't be that difficult to live with.</li> <li>• Well, moderate would be a borderline seeking medication to relieve the pain.</li> <li>• Too much leaning on my arms.</li> </ul>	<ul style="list-style-type: none"> <li>• I would mark severe, because if it's where, to where I have to just kind of hang out and let my hands rest, then I would consider that severe, because I use my hands every day.</li> <li>• Severe to me would be most of the time you were aware of it...</li> <li>• I think that would be very painful; it would give us a lot of pain to have it stinging constantly. I would be quite concerned, I think as you would be quite miserable.</li> <li>• Severe would be taking medication.</li> <li>• I really hit myself hard on the corner, on the edge of a table. That would be severe. My elbows really, My elbows where I have the psoriasis. See with other parts, no. It doesn't matter if I bang it. It's always on the elbows.</li> <li>• Well I think severe is almost the same as very severe, but it might be that it is less often. Not so much, not so aware of it as the very severe.</li> </ul>	<ul style="list-style-type: none"> <li>• I would be crying. If my pain was very severe. My skin would be really thick and cracking and bleeding. Red, very red.</li> <li>• Very severe pain would be like again, I can't manage it. You can't even work...if you had mild, moderate, and severe, I think that would cover it, but so very severe pain would be that your lesions were so painful all the time that you were aware of it.</li> <li>• The burning and the stinging and the cracking would probably all be a very big part of it.</li> <li>• It would be all crazy. You know it is just feeling I cannot sleep. It doesn't...won't go away.</li> <li>• I think it would be very difficult to live with...if you say very severe to me, it is a thing that is going to continue. If it doesn't stop, to me it is very severe.</li> <li>• So if 10 is passing out, I would say very severe for psoriasis would be about a 7 or an 8. Very severe would be seeking medical treatment.</li> <li>• I'd be hurting. I'd really be hurting...A nine, I would consider it a nine.</li> <li>• Very severe is you notice it all the time... You can't do nothing without being aware of the tenderness, the uncomfortableness of it. It is sore.</li> </ul>



Table 4. Patient descriptions of lesion color by Fitzpatrick skin type.

Fitzpatrick score	N (%) of samples	Patient comments about lesion color
6	2 (6.7%)	<ul style="list-style-type: none"> <li>Well it varies. Where I am irritated, it is kind of reddish. Sometimes where psoriasis previously was, sometimes it will be very dark. But in other areas where it was and is gone, it will be lighter than my actual complexion. Those are about the three variations. It is probably just like a red irritated look.</li> </ul>
5	5 (16.7%)	<ul style="list-style-type: none"> <li>Sometimes I notice that the redness is kind of like, I don't know. It's not smooth like the rest of the skin, but it hasn't developed any plaque layers yet. The actual surface of the skin where, like sometimes I can see another spot developing. For psoriasis that appeared from almost nowhere. And so it's just a red spot.</li> <li>The color comes in when it is really like reddish-brown is when I'm suffering from it and when it starts to get lighter and lighter and it almost gets to the color of my skin when it is light. It is a little brownish, but not just brown and then it kind of fades off, you know, the redness fades off when it is either brown or light.</li> <li>It is red. It is turning red and then as it goes, it turns white.</li> </ul>
4	6 (20.0%)	<ul style="list-style-type: none"> <li>Just dry red.</li> <li>Red.</li> <li>Lighter than red.</li> </ul>
3	8 (26.7%)	<ul style="list-style-type: none"> <li>Well after I have bathed, it is all just basically red.</li> <li>Okay, it's pink or red. It may have scaling or flaking, the white cap you might say.</li> <li>Coming from a person that's colorblind, it is red and it is reddish.</li> <li>That deep redness tone, almost the natural color of lymph tissue, of you know if you hit your finger with a hammer, it's going to be that same type of redness level.</li> <li>In general, red. Red and raised.</li> <li>It's kind of normal color, a peach color. The psoriasis affected skin will be redder and possibly even like raised up a little bit. . . . severely infected area . . . Reddish purple.</li> <li>. . . areas that are affected will just be red in the beginning. And then they start to scale after that, within like one or two days.</li> </ul>
2	8 (26.7%)	<ul style="list-style-type: none"> <li>Red. A light orange and red.</li> <li>I'm a pale person so it's a light flesh color. When it first starts flaking it's redder and then it starts fading.</li> <li>It is red skin with white, silvery scales.</li> <li>Bright red spots, scaly spots. Darker red or purple-like, you know.</li> <li>Well, some of it gets very red . . . Well it's pretty much red all the time.</li> </ul>

## Declaration of interest

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