Patient reported symptoms of psoriasis: results from the Psoriasis SELECT Patient Study

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Abstract

- **Background**: Psoriasis Area and Severity Index (PASI) and Physician Global Assessment (PGA) are used frequently to assess treatment benefit in clinical trials for psoriasis treatment. Patient reported symptoms are seldom utilized as a tool to evaluate the benefit of new treatments.

- **Objectives**: In order to better understand the unmet needs of psoriasis patients, a survey was conducted to assess the frequency and importance of patient reported psoriasis symptoms.

- **Methods**: Potential respondents were identified through the 2009 U.S. National Health and Wellness Survey (NHWS) who were 18 and years older with moderate to severe psoriasis (>10% body surface area).

- **Results**: A total of 251 responders with moderate to severe plaque psoriasis completed the survey. The mean age was 49 (20-78) and 63% were female. Of the psoriasis symptoms typically experienced by these patients, 86% were itch, 85% were dry skin, 84% were scaling, 77% were skin redness, 58% were inflammation, and 43% were pain. Of these patients who reported pain, 42% reported non-joint pain, among them, the frequency of the pain were from sometimes to continuous for 87% of the patients, and 81% stated the severity were somewhat painful to extremely painful. In addition, 72% of patients talked to the physician about their non-joint pain, 58% of them used some types of pain relief medications.

- **Conclusion**: Patient reported psoriasis symptoms are important and should be assessed in evaluation of treatment benefit.
Psoriasis is the most prevalent autoimmune disease in the U.S., affecting 7.5 million Americans.\textsuperscript{1}

Direct and indirect healthcare costs are calculated at 11.25 billion annually, with work loss accounting for 40% of that burden.\textsuperscript{2}

60% of psoriasis patients report the disease as a large problem in everyday life,\textsuperscript{3} and 60% of people afflicted with psoriasis miss an average of 26 days of work due to their illness annually.\textsuperscript{4}

Current clinical trial endpoints do not include daily patient self-reported symptoms such as itching, stinging, burning, pain due to cracking, general pain, or scaling.

However, these patient reported symptoms may drive treatment selection for patients due to their burden on daily life and should be included as part of the evaluation in clinical trials.
Objective

In order to better understand the prevalence of these psoriasis symptoms and their impact on patients’ daily lives and activities, a patient survey was conducted to assess:

- severity and botherness of patient self-reported psoriasis related itching, stinging, burning, cracking pain, general pain, and scaling
- the effect of psoriasis symptoms on daily life
- work productivity
A total of 21417 subjects were invited to participate from both National Health and Wellness Survey (NHWS) and The Lightspeed Research (LSR) Ailment Panel (conducted in the U.S. from December 4, 2009- January 7, 2010).

Eligibility criteria: 1) 18 years or older; 2) diagnosis of psoriasis; 3) greater than 10% body surface area currently affected by psoriasis; 4) psoriasis categorized as plaque psoriasis or inverse psoriasis.

The recall period for the psoriasis symptoms and their impact on daily life was 1 day, and the recall period for work productivity questions was 7 days.
Demographic Profile

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Total n = 251</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>63%</td>
</tr>
<tr>
<td>Mean Age (range, SD)</td>
<td>48 years (18-77, 13.4)</td>
</tr>
<tr>
<td>Mean Height (range, SD)</td>
<td>1.70 m (1.50-1.96, 0.09)</td>
</tr>
<tr>
<td>Mean Weight (range, SD)</td>
<td>90.2 kg (39.5-204.1, 26.7)</td>
</tr>
<tr>
<td>Mean BMI (SD)</td>
<td>31 (9)</td>
</tr>
<tr>
<td>Currently Using Medication for Treatment of Psoriasis</td>
<td>89.6%</td>
</tr>
</tbody>
</table>

BMI was calculated by dividing the mass of each individual (kg) by his or her height in meters squared. Height and mass were self-reported by those who took the survey.
Patient reported psoriasis symptoms

Majority of patients (80% to 94%) reported psoriasis symptoms within 24 hours period with a severity and botherness score between 3.6-5.2 on a scale of 0-10.

<table>
<thead>
<tr>
<th></th>
<th>Itching</th>
<th>Stinging</th>
<th>Burning</th>
<th>Skin Cracking</th>
<th>Pain</th>
<th>Scaling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency (%)</td>
<td>94</td>
<td>82</td>
<td>78</td>
<td>81</td>
<td>80</td>
<td>93</td>
</tr>
<tr>
<td>Severity (SD)</td>
<td>5.1 (2.7)</td>
<td>4.0 (3.0)</td>
<td>3.6 (3.0)</td>
<td>3.7 (2.9)</td>
<td>3.8 (2.9)</td>
<td>5.3 (2.8)</td>
</tr>
<tr>
<td>Botherness (SD)</td>
<td>5.1 (2.8)</td>
<td>3.9 (2.9)</td>
<td>3.7 (3.1)</td>
<td>3.8 (3.1)</td>
<td>3.8 (3.1)</td>
<td>5.2 (3.0)</td>
</tr>
</tbody>
</table>

Severity and botherness were reported on a 0-10 scale with 0= no symptoms and 10= symptoms as bad as you can imagine.
Strong correlations between different patient reported psoriasis symptoms

<table>
<thead>
<tr>
<th></th>
<th>Itching</th>
<th>Stinging</th>
<th>Burning</th>
<th>Cracking Pain</th>
<th>General Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity of Stinging</td>
<td>0.72</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severity of Burning</td>
<td>0.67</td>
<td>0.82</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severity of Cracking Pain</td>
<td>0.66</td>
<td>0.64</td>
<td>0.67</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severity of General Pain</td>
<td>0.62</td>
<td>0.67</td>
<td>0.70</td>
<td>0.83</td>
<td></td>
</tr>
<tr>
<td>Severity of Scaling</td>
<td>0.64</td>
<td>0.57</td>
<td>0.56</td>
<td>0.65</td>
<td>0.60</td>
</tr>
</tbody>
</table>
Strong correlations between severity and botherness of each of the patient reported psoriasis symptoms

The regression lines from the other symptoms can be seen below.

- Itching: $y = 0.99x + 0.06$, $R^2 = 0.93$
- Burning: $y = 0.99x + 0.12$, $R = 0.96$
- General Pain: $y = 1.00x + 0.04$, $R = 0.96$
- Stinging: $y = 0.91 + 0.28$, $R = 0.92$
- Cracking Pain: $y = 0.98x + 0.15$, $R^2 = 0.92$
- Scaling: $y = 0.99x - 0.08$, $R = 0.92$

Larger bubble size indicates greater number of responses.
Moderate to strong correlation between severity of psoriasis symptom and avoidance of activity with other people.
Moderate to strong correlation between the severity of psoriasis symptoms and embarrassment about psoriasis.
Impact of psoriasis on work productivity

- Ninety-three (53%) survey responders are currently employed full-time.

<table>
<thead>
<tr>
<th>Full-Time Employees Work Impairment Due to Severe Psoriasis</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Absenteeism (% work time missed due to health, n = 93)</td>
</tr>
<tr>
<td>% Presenteeism (% work impairment due to health, n = 93)</td>
</tr>
</tbody>
</table>

- Of those employed full-time, percentage of people in each division of work productivity loss (% overall work impairment due to health, n=93) is shown. Among all the groups, the average productivity loss was 24% per person.

| None (0%) | 31% |
| Low (1-10%) | 10% |
| Medium (11-30%) | 24% |
| High (31%+) | 23% |
| Mean Productivity Lost per Person | 24% |
Moderate to strong correlation between the severity of psoriasis symptoms and productivity loss

- Self-reported severity of symptoms positively correlated with lost productivity. An example of itching severity vs. productivity loss is seen below. Larger bubble sizes indicates greater number of responses.

Itching vs. Productivity Loss

\[
y = 0.40x + 0.24 \\
R = 0.42
\]

The correlations of all symptoms vs. productivity loss can be seen below.

Severity vs. Work Productivity Loss

- Itching
  \[y = 0.40x + 0.24\]
  \[R = 0.42\]

- Burning
  \[y = 0.51x + 0.33\]
  \[R = 0.57\]

- General Pain
  \[y = 0.51x + 0.30\]
  \[R = 0.57\]

- Stinging
  \[y = 0.43x + 0.50\]
  \[R = 0.51\]

- Cracking Pain
  \[y = 0.47x + 0.48\]
  \[R = 0.52\]

- Scaling
  \[y = 0.23x + 0.97\]
  \[R = 0.25\]
Moderate to strong correlation between the severity of psoriasis symptoms and hours of work missed.

Severity vs. Hours of Work Missed

- Itching: $y = 0.40x - 0.59$, $R = 0.34$
- Stinging: $y = 0.37x - 0.14$, $R = 0.36$
- Burning: $y = 0.44x - 0.26$, $R = 0.41$
- Cracking Pain: $y = 0.44x - 0.30$, $R = 0.40$
- General Pain: $y = 0.50x - 0.51$, $R = 0.45$
- Scaling: $y = 0.27x - 0.09$, $R = 0.23$
Summary

- Despite current treatment (89.6%), the majority of patients (80%-94%) still reported variety of psoriasis symptoms within the previous 24 hours.

- The severity and botherness of these symptoms are moderate to high (mean score between 3.6-5.2 on a scale of 0-10).

- There were moderate to strong correlations between severity of patient reported psoriasis symptoms and
  - their botherness to patients
  - negative impact on patient’s daily life
  - reduced work productivity

- Patient reported psoriasis symptoms are important to patients and should be assessed as part of the evaluation of treatment benefit in clinical trials.
Financial Support

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