Radboud University Nijmegen

PDF hosted at the Radboud Repository of the Radboud University Nijmegen

The following full text is a publisher's version.

For additional information about this publication click this link. http://hdl.handle.net/2066/208359

Please be advised that this information was generated on 2020-09-10 and may be subject to change.



Feasibility and Utility of the Psoriasis Symptom Inventory (PSI) in Clinical Care Settings: A Study from the International Psoriasis Council

Bruce Strober^{1,2} · Peter C. M. van de Kerkhof³ · Kristina Callis Duffin⁴ · Yves Poulin⁵ · Richard B. Warren⁶ · Claudia de la Cruz⁷ · Joelle M. van der Walt⁸ · Bradley S. Stolshek⁹ · Mona L. Martin¹⁰ · Andre V. E. de Carvalho¹¹

Published online: 21 June 2019 © The Author(s) 2019

Abstract

Background The Psoriasis Symptom Inventory (PSI) is a patient-reported outcome measure designed to assess psoriasis signs and symptoms.

Objectives The aim was to assess the usefulness of the PSI in enhancing patient care in the clinical setting.

Methods Eight dermatology clinics in six countries enrolled adults representing the full spectrum of psoriasis severity who regularly received care at the clinic. Patients were administered the eight-item PSI (score range 0–32; higher scores indicate greater severity) while waiting for the physician; the physician conducted a static physician global assessment (sPGA) and estimated psoriasis-affected body surface area (BSA) at the same visit. Physicians completed a brief questionnaire after each patient visit, and were interviewed about the PSI after all patients were seen.

Results The clinics enrolled 278 patients; mean [standard deviation (SD)] psoriasis-affected BSA was 7.6% (11.4). Based on BSA, 47.8% had mild psoriasis, 29.1% had moderate psoriasis, and 23.0% had severe psoriasis. Based on sPGA, 18.7% were clear/almost clear, 67.3% were mild/moderate, and 14.0% were severe/very severe. The mean (SD) PSI total score was 12.2 (8.3). Physicians spent a mean (SD) 4.9 (4.8) min discussing PSI findings with their patients (range 0–20 min). Key benefits of PSI discussions included the following: new information regarding symptom location and severity for physicians; prompting of quality-of-life discussions; better understanding of patient treatment priorities; change in treatment regimens to target specific symptoms or areas; and improvement of patient–physician relationship.

Conclusions The PSI was useful for treated and untreated patients to enhance patient-physician communication, and influenced treatment decisions.

1 Introduction

Psoriasis is a chronic, immune-mediated, hyperproliferative skin disease characterized by erythematous, scaly plaques [1]. Globally, an estimated 100–125 million people suffer from psoriasis [2, 3]. This disease has significant negative impacts on health-related quality of life, most notably on emotional and social domains [4–6]. In a recent National

Bruce Strober strober@centralctderm.com Psoriasis Foundation survey of 5604 patients with psoriasis, 94% reported that psoriasis was a significant problem in daily life [5]. More than 80% reported feelings of selfconsciousness, anger or frustration, helplessness, and embarrassment due to psoriasis [5]. Understanding the impact of psoriasis and the patient's perception of psoriasis is important for developing a patient-centered approach to psoriasis treatment.

The Psoriasis Symptom Inventory (PSI) is a patientreported outcome (PRO) measure that was designed to assess the patient's perception of psoriasis signs and symptoms [7]. The PSI is an eight-item questionnaire that assesses signs and symptoms of itch, redness, scaling, burning, stinging, cracking, flaking, and pain. The severity of each item/sign or symptom is scored on a scale of 0 ("not at all") to 4 ("very severe"); the eight items are summed for a

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s40257-019-00458-2) contains supplementary material, which is available to authorized users.

Extended author information available on the last page of the article

Key Points

The Psoriasis Symptom Inventory (PSI) is a validated patient-reported outcome instrument that was designed to quantify the patient's perception of psoriasis signs and symptoms.

Use of the PSI in real-world dermatology clinics elicited meaningful discussions of psoriasis signs and symptoms between physicians and patients (treated and untreated and across a wide range of disease severity), improved patient perception of the treating physician, and influenced treatment decisions.

The PSI is a validated assessment tool that allows standardized objective evaluation of a patient's perception of psoriasis signs and symptoms, and importantly, improves disease-specific communications between physician and patient.

total score (range 0–32). The PSI is valid, reproducible, and responsive to change [8, 9], and can demonstrate improvements in symptoms with treatment [10]. Two versions with different recall periods were developed and validated: a 24-h recall period and a 7-day recall period [8, 11]. The PSI has undergone cultural/linguistic validation with a wide variety of languages using standard PRO translation methodology (including all languages used in this study) [12, 13].

In a previous study, it was demonstrated that PSI scores were responsive to clinical changes as assessed by the Psoriasis Area and Severity Index (PASI); therefore, PSI score may be useful in monitoring psoriasis severity in the clinic [9]. In a partnership between the International Psoriasis Council (IPC) and Amgen (the developer of the PSI), we tested the utility of the PSI in eight dermatology clinics in six countries that treat and manage patients with psoriasis. In addition to administering the PSI to their regular patients, the physicians at the clinics also filled out a brief questionnaire on each patient interaction, and were subsequently interviewed to discuss their impressions on the use of the PSI. The objective of the study was to assess the usefulness of the PSI in enhancing patient care in the clinical setting.

2 Patients and Methods

2.1 Study Design

This was a noninterventional, international, multicenter, cross-sectional study of the clinical usefulness of physicians' use of the PSI with their patients with plaque psoriasis. Eight global clinical practice sites were selected by the IPC to participate in the study, including three sites in the USA (Farmington, CT; St. Louis, MO; and Salt Lake City, UT) and one site each in the UK (Manchester), the Netherlands (Nijmegen), Brazil (Porto Alegre), Chile (Santiago), and Canada (Quebec City). Study sites regularly treated patients with mild to severe psoriasis. All study sites obtained institutional review board (IRB) approval. All patients provided written informed consent prior to initiation of study-specific procedures.

At a regularly scheduled clinic visit, potentially eligible patients were identified and contacted by clinic staff, completed screening and enrollment, and were administered the paper 7-day recall version of the PSI. Patients were also asked about how much they were currently bothered by psoriasis symptoms, the severity of their current symptoms, the worst severity of their symptoms ever and before treatment, and the location(s) and severity of current psoriasis lesions. During the visit, the physician documented the patient's psoriasis-affected body surface area (BSA) and static physician global assessment (sPGA) score [14], and used the patient's information on the PSI to support discussions about the patient's psoriasis signs and symptoms. After the visit, the physician completed a one-page survey about the visit. After enrollment was closed at each site (upon enrollment of ~35 patients), the participating physicians completed a 20-30-min qualitative telephone interview.

2.2 Patients

To be eligible, patients were adults (\geq 18 years of age), had physician-confirmed diagnosis of mild to severe plaque psoriasis, and were able to complete the PSI and discuss their symptoms with their physician. Patients who had any clinically relevant condition, were receiving treatment that could interfere with the patient's ability to focus their responses on psoriasis symptoms, or were enrolled in a psoriasis investigational drug study were excluded. Enrollment was monitored to assure a distribution of ~40% mild psoriasis (affected BSA 0–4%), ~40% moderate psoriasis (BSA 5–9%), and ~20% severe psoriasis (BSA \geq 10%), and that ~50% of the population was treatment naïve as well as balanced for demographic characteristics of sex and age.

2.3 Study Outcomes

The primary outcome was the physician experiences on the usefulness of the PSI based on physician surveys and interviews. The physician survey included questions about the length of time spent discussing the PSI, if other psoriasis symptoms were discussed, if any new information was obtained from the discussion, if the PSI data enhanced the discussion or interaction with the patient, any benefits that the PSI provided toward patient care, and if the PSI was useful to have during the visit. The qualitative interview was based on a structured interview guide, which used openended, exploratory questions by trained interviewers. Physician interviews were audio recorded, transcribed, and summarized. The transcripts were used to extract key quotations and summary statements against specific questions discussed during the interview process.

3 Results

3.1 Patients

Across the eight study sites, 278 patients were enrolled in the study. The mean [standard deviation (SD)] age was 47.5 (14.0) years; 57.9% of the patients were male (Table 1). Additional demographic information is shown in Supplemental Table S1. Based on affected BSA, 47.8% of patients had mild psoriasis (range 40.0–67.5% across all sites), 29.1% had moderate psoriasis (range 12.5–40.0%), and 23.0% had severe psoriasis (range 17.5–42.9%). Across all patients, 18.7% had an sPGA score 0–1 (clear–almost clear) (range 2.9–28.6% across all sites), 67.3% had an sPGA score 2–3 (mild–moderate) (range 42.9–91.4%), and 14.0% had an sPGA score 4–5 (severe–very severe) (range 0–37.1%). Forty-nine patients (17.6%) were treatment-naïve or receiving no treatment for their psoriasis.

The mean (SD) PSI total score for all patients was 12.2 (8.3). Mean PSI item scores differed by study site, but all were within the range of SDs from the US validation study (Fig. 1) [8]. PSI total scores also differed by study site (range 10.3–14.9); study sites with a greater percentage of patients who had severe disease reported higher mean PSI total scores. The mean (SD) PSI total scores by study site were 12.6 (8.4) for CT, USA; 10.6 (7.9) for MO, USA; 13.3 (8.8) for UT, USA; 11.7 (9.2) for the UK; 10.5 (7.5) for the Netherlands; 14.9 (8.1) for Brazil; 12.9 (9.1) for Chile; and 10.3 (6.8) for Canada. Based on PSI total score categories, 107 patients (38.5%) had no/mild symptoms (PSI total score 0-8), 89 (32.0%) had moderate symptoms (PSI total score 9-16), 57 (20.5%) had severe symptoms (PSI total score 17-24), and 25 (9.0%) had very severe symptoms (PSI total score 25-32).

3.2 Physician Surveys

The PSI was considered to be a useful tool during the clinic visit for three-quarters of the participating patients. Overall, physicians spent a mean (SD) of 4.9 (4.8) min discussing the PSI with their patients (range 0–20 min). The amount of time spent discussing the PSI varied based on PSI total score category (none/mild, moderate, severe, and very severe)

and treatment status (treated and treatment naïve). The mean (SD) time for treated patients was 3.4 (3.8) min for patients with none/mild symptoms, 5.1 (4.4) min for patients with moderate symptoms, 5.8 (6.6) min for patients with severe symptoms, and 6.7 (5.5) min for patients with very severe symptoms. The mean (SD) time for treatment-naïve patients was 6.1 (5.1) min for patients with none/mild symptoms, 4.5 (4.6) min for patients with moderate symptoms, 4.9 (4.7) min for patients with severe symptoms. The mean (3.2 min for patients with 3.4 (3.8) min for patients with 3.4 (3.8 (3

In the surveys, physicians noted that symptoms not usually discussed in routine visits were discussed in the context of the PSI, and patients were encouraged to discuss new information (Table 2). In some cases, physicians noted that the use of the PSI appeared to improve the patient–physician relationship.

3.3 Physician Interviews

In qualitative interviews, all eight physicians endorsed the PSI as an aid in patient-physician interactions regarding psoriasis disease management (Table 3). The PSI was determined to be useful for many reasons. There was a low time burden (less than 5 min) to discuss the information. The physicians obtained a better understanding of the patientspecific experiences related to psoriasis and often re-examined patient priorities for treatment. Over time, the PSI could be used to document progress in treatment satisfaction. The physicians also noted several benefits for patients with the use of the PSI. The instrument provided the patients with the ability to rate their symptoms in writing (which puts less pressure on the patient), the symptoms were provided in the instrument, and patients were less likely to underreport symptoms in the time-sensitive context of a clinic visit. Patients were able to address sensitive issues such as genital symptoms. Patients also discussed quality-of-life aspects as they related to their psoriasis signs and symptoms, and some patients were able to use PSI symptom ratings to alert the physician to their distress from their psoriasis signs and symptoms when they had been previously unable to do so verbally. Physicians, who generally focused on lesion size, were frequently directed to a specific lesion location when a sign or symptom was rated as severe by the patient. The PSI appeared to be particularly useful in driving communication with patients with low verbal aptitude. Physicians noted that the PSI discussions affected some treatment decisions. For example, one physician added topical therapy for specific lesions in patients who were receiving biologic therapies, and one physician opted for more aggressive regimens when the PSI score was high in patients with low affected BSA.

Table 1 Patient characteristics	aracteristics								
	CT, USA $(n=35)$	MO, USA $(n=24)$	UT, USA $(n=40)$	UK $(n = 35)$	Netherlands $(n=35)$	Brazil $(n=35)$	Chile $(n=35)$	Canada $(n=39)$	All patients $(N=278)$
Age, mean years (SD) [range]	48.1 (14.2) [19–76]	44.0 (12.5) [19–70]	41.1 (15.7) [18–85]	42.7 (9.1) [24–69]	50.1 (12.5) [19–71]	52.6 (12.7) [25–76]	44.2 (12.9) [18–74]	55.3 (14.5) [26–87]	47.5 (14.0) [18–87]
Sex, <i>n</i> male (%)	25 (71.4)	15 (62.5)	17 (42.5)	21 (60.0)	13 (37.1)	21 (60.0)	23 (65.7)	26 (66.7)	161 (57.9)
Race, n (%)									
White	28 (80.0)	22 (97.1)	40 (100)	30 (85.7)	31 (88.6)	32 (91.4)	2 (5.7)	38 (97.4)	223 (80.2)
African Ameri- can/black	0	1 (4.2)	0	0	4 (11.4)	2 (5.7)	0	0	7 (2.5)
Asian	3 (8.6)	0	0	4 (11.4)	0	0	0	1 (2.6)	8 (2.9)
Hispanic, Latino, Span- ish	4 (11.4)	0	0	0	0	1 (2.9)	33 (94.3)	0	38 (13.7)
Missing	0	1 (4.2)	0	1 (2.9)	0	0	0	0	2 (0.7)
Duration of	15.4 (14.2)	16.4 (10.0)	13.6 (11.7)	21.0 (13.6)	19.1 (16.3)	16.9 (12.2)	15.1 (13.5)	23.4 (15.5)	17.7 (13.8)
plaque psoria- sis, mean years (SD) [range]	[0.5-60]	[2-35]	[0.5-50]	[0.8–53]	[2-58]	[0.8–55]	[0.2-55]	[1-61]	[0.2-61.0]
sPGA category, n (%)	(%)								
0–1 (clear– almost clear)	8 (22.9)	6 (25.0)	8 (20.0)	10 (28.6)	3 (8.6)	1 (2.9)	9 (25.7)	7 (17.9)	52 (18.7)
2–3 (mild–mod- 19 (54.3) erate)	19 (54.3)	18 (75.0)	27 (67.5)	15 (42.9)	32 (91.4)	21 (60.0)	23 (65.7)	32 (82.1)	187 (67.3)
4–5 (severe- very severe)	8 (22.9)	0	5 (12.5)	10 (28.6)	0	13 (37.1)	3 (8.6)	0	39 (14.0)
Psoriasis-affected 6.0 (5.7) [1–30] BSA, mean % (SD) [range]	6.0 (5.7) [1–30]	5.3 (6.7) [0–25]	4.5 (5.9) [0–32]	11.0 (13.9) [0–75]	6.6 (6.0) [0–31]	11.4 (19.0) [1–80]	10.0 (16.6) [0–70]	6.5 (7.8) [0–37]	7.6 (11.4) [0–80]
BSA category, n (%)	(%								
0-4%	14 (40.0)	15 (62.5)	27 (67.5)	14 (40.0)	14(40.0)	14 (40.0)	14 (40.0)	21 (53.8)	133 (47.8)
5-9%	14 (40.0)	3 (12.5)	6 (15.0)	6 (17.1)	14(40.0)	14 (40.0)	14 (40.0)	10 (25.6)	81 (29.1)
≥ 10%	7 (20.0)	6 (25.0)	7 (17.5)	15 (42.9)	7 (20.0)	7 (20.0)	7 (20.0)	8 (20.5)	64 (23.0)
Comorbid pso- riatic arthritis, <i>n</i> (%)	14 (40.0)	7 (29.2)	4 (10.0)	11 (31.4)	10 (28.6)	10 (28.6)	10 (28.6)	8 (20.5)	74 (26.6)
Treatment status, n (%)	1 (%)								
Treatment- naïve/none	10 (28.6)	1 (4.2)	13 (32.5)	0	0	17 (48.6)	6 (17.1)	2 (5.1)	49 (17.6)
Biologic treat- ment	10 (28.6)	12 (50.0)	14 (35.0)	20 (57.1)	16 (45.7)	8 (22.9)	10 (28.6)	20 (51.3)	110 (39.6)
Other treatment 15 (42.9)	15 (42.9)	11 (45.8)	13 (32.5)	15 (42.9)	19 (54.3)	10 (28.6)	19 (54.3)	17 (43.6)	119 (42.8)

Table 1 (continued)	1)								
	CT, USA $(n=35)$	MO, USA $(n=24)$	UT, USA $(n=40)$	UK $(n=35)$	Netherlands $(n=35)$	Brazil $(n=35)$	Chile $(n=35)$	Canada $(n=39)$	All patients $(N=278)$
Current level of bother from psoriasis symptoms, mean score on 0-10 NRS (SD) [range]	6.6 (3.1) [0–10]	5.2 (3.5) [0–10]	5.7 (3.2) [1–10]	5.0 (3.4) [0–10]	5.2 (2.7) [1–10]	8.4 (2.6) [1–10]	6.2 (2.9) [0–10]	4.9 (3.5) [0–10]	5.9 (3.3) [0–10]
Current severity of psoriasis symptoms, mean score on 0-10 NRS (SD) [range]	5.8 (3.2) [0–10]	4.2 (2.9) [0–10]	5.2 (3.2) [0–10]	4.2 (3.3) [0-10]	4.6 (2.7) [1–10]	7.3 (2.9) [0–10]	5.2 (3.3) [0–10]	4.1 (3.0) [0–10]	5.1 (3.2) [0–10]
Worst ever sever- ity of psoriasis symptoms, mean score on 0-10 NRS (SD) [range]	8.4 (2.0) [2–10]	8.4 (1.5) [5–10]	8.6 (1.4) [4–10]	9.4 (1.0) [7–10]	8.9 (1.2) [6–10]	7.6 (2.9) [1–10]	7.0 (2.8) [0–10]	7.9 (2.1) [0–10]	8.3 (2.1) [0–10]
Worst ever sever- ity of psoriasis symptoms before treat- ment, mean score on 0–10 NRS (SD) [range]	7.9 (2.2) [2–10]	7.5 (2.5) [0–10]	8.2 (2.0) [2–10]	8.7 (1.8) [3–10]	8.1 (21.1) [1–10]	9.1 (1.6) [3–10]	7.7 (2.5) [0–10]	7.8 (2.2) [0–10]	8.2 (2.1) [0–10]
PSI, mean total score (SD) [range]	12.6 (8.4) [1–28]	12.6 (8.4) [1–28] 10.6 (7.9) [0–25]	13.3 (8.8) [0–32]	11.7 (9.2) [0–32] 10.5 (7.5) [0–28]		14.9 (8.1) [2–32] 12.9 (9.1) [0–29]	12.9 (9.1) [0–29]	10.3 (6.8) [0–24]	12.2 (8.3) [0–32]
PSI item scores, mean (SD)	ean (SD)								
Item 1, itch	1.7 (1.3)	1.6 (1.2)		1.7(1.3)	1.7 (1.2)	2.1 (1.3)	1.9(1.3)	1.3 (0.9)	1.7 (1.2)
Item 2, redness	2.1 (1.0)	1.8 (1.2)	2.0 (1.2)	1.8 (1.3)	2.0 (1.2)	2.3 (0.9)	2.0 (1.2)	1.9(1.0)	2.0 (1.1)
Item 3, scaling	2.2 (1.1)	1.6(1.1)	2.0(1.1)	1.8 (1.2)	1.4 (1.2)	2.0 (1.2)	1.6 (1.2)	1.5(0.9)	1.8 (1.2)
Item 4, burning	1.0 (1.2)	1.0(1.1)	1.4(1.2)	1.1 (1.2)	1.3 (1.3)	1.8 (1.3)	1.1 (1.3)	0.9(1.1)	1.2 (1.2)
Item 5, stinging	1.0 (1.2)	1.0(1.0)	1.3 (1.2)	1.2 (1.3)	0.7 (1.1)	1.3(1.1)	1.3(1.3)	1.2(1.0)	1.1 (1.2)
Item 6, cracking	1.5(1.3)	1.1 (1.2)	1.7 (1.2)	1.3 (1.3)	0.7 (1.1)	1.7 (1.4)	1.6(1.4)	1.1(1.0)	1.4(1.3)
Item 7, flaking	2.0 (1.2)	1.5 (1.2)	_	1.6 (1.2)	1.6 (1.3)	2.3 (1.3)	2.0 (1.3)	1.3(1.1)	1.8 (1.3)
Item 8, pain	1.1 (1.3)	1.0 (1.0)	1.3 (1.2)	1.2 (1.3)	1.1 (1.1)	1.5 (1.5)	1.4 (1.4)	1.1 (0.9)	1.2 (1.2)

∆ Adis

U U
-
=
8
· = -
=
8
0
~
\sim
\smile
\leq
-
e 1
e e
e e
e e

lable I (continued)	(D)								
	CT, USA $(n=35)$	MO, USA $(n=24)$	UT, USA $(n=40)$	UK $(n=35)$	Netherlands $(n=35)$	Brazil $(n=35)$	Chile $(n=35)$	UK $(n=35)$ Netherlands Brazil $(n=35)$ Chile $(n=35)$ Canada $(n=39)$ All patients $(n=35)$ $(n=35)$ $(N=278)$	All patients $(N=278)$
Length of time discussing PSI with physician, mean minutes (SD) [range]	2.3 (1.2) [1–7]	2.3 (1.2) [1–7] 5.9 (3.3) [0–10] 1.8 (1.3)	1.8 (1.3) [0–5]	[0-5] 3.3 (2.3) [0-10] 3.5 (2.2) [0.5-10] 5.5 (2.8) [1-12] 15.3 (4.2) [10-20]	3.5 (2.2) [0.5–10]	5.5 (2.8) [1–12]	15.3 (4.2) [10–20]	2.4 (4.2) [1–5]	2.4 (4.2) [1–5] 4.9 (4.8) [0–20]

IJ BSA body surface area, CT Connecticut, MO Missouri, NRS numeric response scale, PSI Psoriasis Symptom Inventory, SD standard deviation, sPGA static physician global assessment, Utah

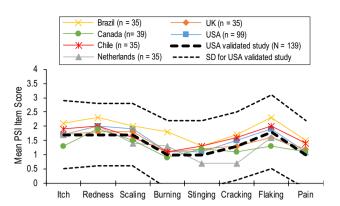


Fig. 1 Mean PSI item scores by study site. Mean item scores are shown for study sites in Brazil (yellow), Canada (green), Chile (red), the Netherlands (gray), the UK (orange), the US sites (data from 3 sites pooled; blue), and the US study used to validate the PSI [8] (bold hashed line). Upper and lower dashed lines represent SDs for the US validation study. PSI Psoriasis Symptom Inventory, SD standard deviation

4 Discussion

In this study of the use of the PSI in the setting of routine clinical practice, we made three key observations. First, physicians received new information about their patients' perceptions of psoriasis symptoms. For example, patients who appeared to the physician to have mild disease overall sometimes rated specific symptoms as very severe or noted symptoms in problem areas. Second, the PSI information helped with making decisions about care. In some instances, topical therapies were added to problem areas, and in some instances, systemic therapy was initiated. Third, the burden of the instrument was low for the patient and for the physician. Patients completed the instrument while waiting to see the physician, and the physicians required only 5 min on average during the visit to review the results.

Physicians and patients use different measures to estimate psoriasis severity in both clinical trials and in clinical practice. In psoriasis clinical trials, the PASI is the most commonly used measure of psoriasis severity and the Dermatology Life Quality Index (DLQI) is the most common measure of patient-reported health-related quality of life [15]. In clinical practice, physicians focus on elements of the PASI (e.g., size and appearance of lesions), whereas patients tend to focus on the location of lesions and impact of the disease on their lives. The correlation between improvements in psoriasis lesions (as measured by PASI) and improvements in quality of life (as measured by DLQI) varies, with some studies showing weak correlations [16, 17].

A recent study of patients enrolled in the Swedish psoriasis registry (PsoReg) showed that the decision to initiate systemic therapy was more strongly associated with the patient's PASI score than with DLQI results [18]. While this

Table 2	Physician	surveys to	evaluate	PSI	usefulness	in	clinical	practice

	Physician response of yes, n (%)
Symptoms that were not usually covered in routine visits were discussed	94 (33.8)
Physicians found that patients were encouraged to bring forward new information for discussion	157 (56.5)
The new information was helpful in making better decisions about each patient's care	185 (66.5)
Overall, the use of the PSI was helpful during the patient visit	209 (75.2)

PSI Psoriasis Symptom Inventory

approach is appropriate for most patients, patients with a low affected BSA who rated their disease as moderate to severe (~30% of patients in a recent survey [19]) represent a patient population that is likely to be undertreated. Patients with a single severe symptom (such as itch [20, 21]) or with lesions in certain areas (such as visible areas [22]) may report poor quality of life and yet have a low PASI score. A recent survey of dermatologists showed that the level of treatment satisfaction for approximately one in five patients was misaligned with the physician's level of satisfaction with treatment [23]. These patients reported a poorer quality of life and more severe symptoms than the patients who were aligned with their physicians. Patients are reliable in the assessment of their disease severity [19, 24, 25]. These observations support a growing call for better communication between physicians and patients to achieve optimal treatment regimens, which improve quality of life [6, 26-28]. In particular, it has been suggested that physicians need to carefully evaluate the impacts of signs and symptoms on patients [19].

Differences in PSI item and total scores were noted between geographic regions, although statistically all values were within the SDs for item and total scores recorded in the validation study. For five of the eight PSI item scores, Latin American sites (Brazil and Chile) had the highest mean scores, which may reveal a significant cultural difference. While we do not know the specific reasons for these differences, ethnic and racial differences may potentially impact the perception and effects of psoriasis symptoms. Additionally, quality of life and standards of living vary geographically, which may impact perception of disease severity based on the geographic location of the patient. Cultural and geographic differences in the patient-physician relationship may also exist, and the PSI could potentially normalize these differences cross-culturally. Further studies in larger real-world populations are needed to understand these differences.

Differences were also seen in the time spent discussing the PSI based on PSI total scores. In both treated and treatment-naïve patients, the time spent discussing the PSI was longer in patients who had rated their symptoms as more severe on the PSI compared to patients with no/mild symptoms. Physicians may therefore consider the PSI score as an indication of the amount of time that may be required for a particular patient visit. Overall, the investigators responded that patients with severe psoriasis required more time during the clinical evaluation to discuss symptom scores. For example, among the treated group, a mean (SD) of 5.8 (6.6) min was spent on patients with severe symptoms, and among the treatment-naïve group, 4.9 (4.7) min was spent on patients with severe symptoms. Notably, for patients with high PSI scores, a higher proportion of physicians noted that the PSI discussions assisted with decision on care and were useful to have during the visit (data not shown). The PSI may therefore be particularly useful for patients with severe/very severe disease.

There were some limitations to this study. Both the physicians and the patients were aware that the PSI was administered as part of a clinical survey, which could have introduced a bias towards favorable impressions of the instrument. The generalizability of the PSI usefulness may be restricted because the data were collected in referral centers focused on the treatment of psoriasis. An instrument that adds a 5-min discussion to a clinic visit could be construed as too burdensome for some physicians or patients. Some patients' symptoms may be deliberately overestimated to increase the likelihood of obtaining systemic (primarily biologic) treatments; this may be driven by access to health care in some countries. Psoriatic arthritis, a common comorbidity in patients with psoriasis, is not addressed in the PSI, which assesses skin symptoms but not joint symptoms. The study did not address conversations about psoriatic arthritis in the physician surveys or interviews. Finally, although the overall sample size was large, the sample sizes of individual regions were too small to allow regional comparisons.

A strength of the study was the relatively large patient population that was recruited across several countries. Patients represented a wide range of disease severity and treatments, and the population was reasonably balanced among treatment-naïve and treatment-experienced patients and across genders. The global distribution of study sites allows for external validity of the instrument. The use of the PSI provides opportunities for working in the virtual

ы

 Table 3
 Select quotes from physician interviews

Interview topic	Select quotes			
What was your overall experience with the PSI in this study?	 "It just helped to direct consultations, fairly rapidly, to problem areas, and the main observation was, patients who I've been seeing for many, many years, actually aren't necessarily volunteering these things" "[A]llowed the treating practitioner to understand the effect of the disease state symptomatically on the patient. That went beyond what we could necessarily glean from our typical approaches to seeing patients with psoriasis." 			
Were there changes in how patients understood or discussed the severity of their psoriasis?	"Sometimes the patient really doesn't want to speak about their disease, or the appearance, and when they are feeling depression they can express somethingthey do not want to sayin their own mind they can do that in writing and they cannot do that in speaking."			
Were there changes in how you perceived the patient's perception of the severity of their psoriasis?	"There were many times when the PSI outcome seemed very different from what I would expect.""I have no other way of knowing how severe their symptoms are if they don't tell me and so it provided a more objective place to start""[F]or some patients therewas far greater distress from symptoms than I was anticipating."			
What were some benefits of using the PSI dur- ing your discussions with patients?	 "[I]t's nice to have a number to quantify their symptoms." "[O]n a more, sort of global level, I think was aware that many patients have a lot of distress from their psoriasis." "We clearly interact, now with the patient, and how the patient felt about their lesions." 			
Describe any change in how the patients com- municated with you.	"I think that it was really something that will help to improve the conversation and the relation between patient and doctor." "[W]e often will express itch but I think it was a validation of the fact that the psoriasis symptoms are more than just itch or pain, that it can be stated different ways, and I think they appreciated that"			
How did the patient's understanding of sever- ity compare to their diagnosis?	"[T]he severity indicated by the questionnaire, the ultimate score that I got back, was in disagreementwith the results of examinationthe PSI outcome seemed very different from what I would expect." "[T]he patients are affected by, sometimes, the particular site, like forearms, or the hands, or the lesion on the neck, where it appears morefound that it was worse from the patient's point of view."			
Were there any surprises for you in discussing severity with patients?	"I wouldn't say surprises but the burning symptom was brought up more than I thought." "Yes, I would say, at least, a third to half of patients that we enrolled I felt somewhat surprised by the discrepancy between what I thought they would have and what they actually had as a score on the PSI. First the total score could be surprising, let's say I predicted they'd have a 12 and they came back with a 23." "[I]f the patient might calmly state, yes, I experience itch, you might think, well, they're not really emphasizing that symptom. But thenthey score the itch domain in the PSI, they give it either a 3 or 4."			
Were there any problematic or beneficial trends that you noticed?	"Sometimes not with the bigger lesions, but where the lesions are, and it really affect patients." "Itchingthat came out, the burning sensationthere were more patients talking about that than we expected."			
Did you notice any trends about symptoms that were most upsetting to patients?	"It affects their sleeping at night. It affects their relations with their partners" "[G]enital involvement psoriasis" "The burning sensation is something that, it's not a rare thing, but it's not that common." "Anything that shows up on the face is always on their mind."			
Overall, did the PSI represent what patients' symptoms were like?	"[I]t was proof to methe eight domains are highly relevant to the physical experience of hav- ing psoriasis."			
Were the discussions about the PSI useful?	"I think the net effect was positive, given the time required for the patient to complete the PSI was minimal, and the information gleaned from the results of the PSI was, on balance, very helpful." "This is a good representation of what the patient is now at the moment we speak."			
How did the PSI enhance patient care, if at all?	"I think that it was an advantage specifically because it doesn't take me so much longer and I can go deeper in the relation with the patient.""Yes, because many of the domains of the PSI are not commonly assessed in your average dermatology visit."			

Table 3 (continued)

Interview topic	Select quotes
Were there changes to treatment plans based on the information in the PSI?	 "For example, patients with low BSA score butin the questionnairehad an impact on their quality or lifeI would go more aggressive in choosing a treatment." "It's very useful to learn about the value of the Psoriasis Symptoms Index in the detecting the need for a change." "But, what I did find is that I did refine some of the topical measures that I was prescribing
	it tended to be site-specific issues for patientsthe genital diseaseor one highly pruritic patch""I do think it has the ability to help drive a conversation to escalate or de-escalate therapy."
Were there discussions about quality of life prompted by the PSI process itself?	"For introspective patients, patients that do not speak a lot, or don't like to speak a lot or have very, very low self-esteem the questionnaire just brought up a lot of issues that we could not get from them in other ways."
Did the discussions about PSI results bring to light any new information?	"[O]ne of my patients had very limited body surface area but her scores were so severe that it kind of surprised meother peoplehad a lot of psoriasis but their scores were a little bit lower."

BSA body surface area, PSI Psoriasis Symptom Inventory

environment. Patient-reported severity is condensed to a single-digit assessment. Importantly, the instrument can be used to document a treatment response.

5 Conclusion

In conclusion, the PSI has the potential to improve dermatologic practice by providing a comprehensive tool to assess psoriasis symptoms. In this study, physicians endorsed the usefulness of the PSI to discuss symptoms and symptom impacts in routine clinic visits. The discussions informed treatment decisions and enhanced physician-patient relationships. Despite the greater amount of time spent discussing the PSI in patients with more severe disease, physicians treating those patients reported an influence of the PSI discussion on treatment decisions. The PSI may improve communication between physicians and patients and provide an option for quality monitoring.

Acknowledgements Dikran Toroser (Amgen Inc.) and Julia R. Gage (on behalf of Amgen Inc.) provided medical writing support. This research was supported by a grant from Amgen, and R.B. Warren is supported by the NIHR Manchester Biomedical Research Centre.

Compliance with Ethical Standards

Funding This study was sponsored by Immunex, a wholly owned subsidiary of Amgen Inc.

Conflict of interest *B. Strober* serves as a consultant for AbbVie Inc., Almirall, S.A., Amgen Inc., AstraZeneca, Celgene Corp., Dermira, Inc., Janssen Global Services, LLC, LEO Pharma Inc., Eli Lilly & Co., GlaxoSmithKline, plc, Medac Pharma Inc., Menlo Therapeutics, Novartis AG, Pfizer Inc., UCB, Sun Pharma, and Ortho Dermatologics/Valeant Pharmaceuticals; is an investigator for AbbVie Inc., Boehringer Ingelheim, Celgene Corp., Eli Lilly & Co., Galderma S.A., Janssen Global Services, LLC, Merck & Co., Inc., and Sienna Biopharmaceuticals; serves as Scientific Director for the Corrona Psoriasis Registry; and has received grant support to the University of Connecticut Fellowship Program from AbbVie Inc. and Janssen Global Services, LLC. P.C.M. van de Kerkhof is a consultant for Abbott Laboratories, Almirall, S.A., Amgen Inc., Celgene Corp., Centocor, Eli Lilly & Co., Galderma S.A., Janssen-Cilag, LEO Pharma Inc., Mitsubishi Tanabe Pharma America, Inc., Novartis AG, Pfizer Inc., Koninklijke Philips N.V., and Sandoz International GmbH; and is an investigator for AbbVie Inc., Amgen Inc., Basilea Pharmaceutica Ltd., Eli Lilly & Co., Janssen-Cilag, LEO Pharma Inc., Koninklijke Philips N.V., and Pfizer Inc. K. Callis Duffin has received research grants from AbbVie Inc., Amgen Inc., Celgene Corp., Eli Lilly & Co., Janssen Global Services, LLC, Novartis AG, Pfizer Inc., Sienna Biopharmaceuticals, and Stiefel Laboratories, Inc.; and has received consulting fees from AbbVie Inc., Amgen Inc., Celgene Corp., Eli Lilly & Co., Janssen Global Services, LLC, Novartis AG, Pfizer Inc., Sienna Biopharmaceuticals, and Stiefel Laboratories, Inc. Y. Poulin has received research grants from Boehringer Ingelheim, Bristol-Myers Squibb, Celgene Corp., Eli Lilly & Co., Galderma S.A., GlaxoSmithKline plc, LEO Pharma Inc., MedImmune, Merck & Co., Inc., Novartis AG, Pfizer Inc., Regeneron, and UCB; and serves on speakers bureaus for AbbVie Inc., Amgen Inc., Eli Lilly & Co., Novartis AG, and Sanofi Genzyme. R.B. Warren has received research grants from AbbVie Inc., Almirall, S.A., Amgen Inc., Celgene Corp., Eli Lilly & Co., Janssen Global Services, LLC, LEO Pharma Inc., Novartis AG, Pfizer Inc., and UCB; and is a consultant for AbbVie Inc., Almirall, S.A., Amgen Inc., Boehringer Ingelheim, Celgene Corp., Eli Lilly & Co., Janssen Global Services, LLC, LEO Pharma Inc., Novartis AG, Pfizer Inc., Sanofi, XenoPort, Inc., and UCB. C. de La Cruz has received research grants from AbbVie Inc., Amgen Inc., Coherus Biosciences, Eli Lilly & Co., Genentech, Neovacs S.A., Novartis AG, and Pfizer Inc.; and is a consultant for AbbVie Inc., Janssen Global Services, LLC, Novartis AG, and Pfizer Inc. J. van der Walt has no conflicts to declare. B.S. Stolshek is an employee and shareholder of Amgen Inc. M.L. Martin is an employee of Health Research Associates, Inc., which received funding from Amgen Inc. to conduct this study. A.V.E. de Carvalho has received research grants from Amgen Inc. and serves on speakers bureaus for Janssen Global Services, LLC, Novartis AG, and Pfizer Inc.

Open Access This article is distributed under the terms of the Creative Commons Attribution-NonCommercial 4.0 International License (http://creativecommons.org/licenses/by-nc/4.0/), which permits any

noncommercial use, distribution, and reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made.

References

- Weigle N, McBane S. Psoriasis. Am Fam Physician. 2013;87:626–33.
- World Health Organization. Global report on psoriasis [WWW document]. http://apps.who.int/iris/bitstream/10665/20441 7/1/9789241565189_eng.pdf. Accessed 13 June 2019.
- International Federation of Psoriasis Associations. Our cause: psoriasis [WWW document]. https://ifpa-pso.com/our-cause/. Accessed 13 June 2019.
- Pariser D, Schenkel B, Carter C, et al. A multicenter, non-interventional study to evaluate patient-reported experiences of living with psoriasis. J Dermatolog Treat. 2016;27:19–26.
- Armstrong AW, Schupp C, Wu J, et al. Quality of life and work productivity impairment among psoriasis patients: findings from the National Psoriasis Foundation survey data 2003-2011. PLoS One. 2012;7:e52935.
- Bhosle MJ, Kulkarni A, Feldman SR, et al. Quality of life in patients with psoriasis. Health Qual Life Outcomes. 2006;4:35.
- Martin ML, McCarrier KP, Chiou CF, et al. Early development and qualitative evidence of content validity for the Psoriasis Symptom Inventory (PSI), a patient-reported outcome measure of psoriasis symptom severity. J Dermatolog Treat. 2013;24:255–60.
- Bushnell DM, Martin ML, McCarrier K, et al. Validation of the Psoriasis Symptom Inventory (PSI), a patient-reported outcome measure to assess psoriasis symptom severity. J Dermatolog Treat. 2013;24:356–60.
- 9. Revicki DA, Jin Y, Wilson HD, et al. Reliability and validity of the Psoriasis Symptom Inventory in patients with moderate-to-severe psoriasis. J Dermatolog Treat. 2014;25:8–14.
- Gordon KB, Kimball AB, Chau D, et al. Impact of brodalumab treatment on psoriasis symptoms and health-related quality of life: use of a novel patient-reported outcome measure, the Psoriasis Symptom Inventory. Br J Dermatol. 2014;170:705–15.
- 11. Viswanathan HN, Mutebi A, Milmont CE, et al. Measurement properties of the Psoriasis Symptom Inventory electronic daily diary in patients with moderate to severe plaque psoriasis. Value Health. 2017;20:1174–9.
- Wild D, Grove A, Martin M, et al. Principles of good practice for the translation and cultural adaptation process for patientreported outcomes (PRO) measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value Health. 2005;8:94–104.
- 13. Wild D, Eremenco S, Mear I, et al. Multinational trials-recommendations on the translations required, approaches to using the same language in different countries, and the approaches to support pooling the data: the ISPOR Patient-Reported Outcomes Translation and Linguistic Validation Good Research Practices Task Force report. Value Health. 2009;12:430–40.

- 14. Pascoe VL, Enamandram M, Corey KC, et al. Using the Physician Global Assessment in a clinical setting to measure and track patient outcomes. JAMA Dermatol. 2015;151:375–81.
- Garduno J, Bhosle MJ, Balkrishnan R, et al. Measures used in specifying psoriasis lesion(s), global disease and quality of life: a systematic review. J Dermatolog Treat. 2007;18:223–42.
- Schafer I, Hacker J, Rustenbach SJ, et al. Concordance of the Psoriasis Area and Severity Index (PASI) and patient-reported outcomes in psoriasis treatment. Eur J Dermatol. 2010;20:62–7.
- 17. Griffiths CE, Sterry W, Brock F, et al. Pattern of response in patients with moderate-to-severe psoriasis treated with etanercept. Br J Dermatol. 2015;172:230–8.
- Hagg D, Sundstrom A, Eriksson M, et al. Decision for biological treatment in real life is more strongly associated with the Psoriasis Area and Severity Index (PASI) than with the Dermatology Life Quality Index (DLQI). J Eur Acad Dermatol Venereol. 2015;29:452–6.
- Korman NJ, Zhao Y, Li Y, et al. Clinical symptoms and selfreported disease severity among patients with psoriasis -Implications for psoriasis management. J Dermatolog Treat. 2015;26:514–9.
- Globe D, Bayliss MS, Harrison DJ. The impact of itch symptoms in psoriasis: results from physician interviews and patient focus groups. Health Qual Life Outcomes. 2009;7:62.
- Zhu B, Edson-Heredia E, Guo J, et al. Itching is a significant problem and a mediator between disease severity and quality of life for patients with psoriasis: results from a randomized controlled trial. Br J Dermatol. 2014;171:1215–9.
- Heydendael VM, de Borgie CA, Spuls PI, et al. The burden of psoriasis is not determined by disease severity only. J Investig Dermatol Symp Proc. 2004;9:131–5.
- Korman NJ, Zhao Y, Pike J, et al. Satisfaction with current psoriasis treatment: misalignment between physician and patient perceptions. Dermatol Online J. 2016;22. Retrieved from https://escho larship.org/uc/item/7405k1nn.
- Feldman SR, Fleischer AB Jr, Reboussin DM, et al. The selfadministered psoriasis area and severity index is valid and reliable. J Investig Dermatol. 1996;106:183–6.
- 25. Sampogna F, Sera F, Mazzotti E, et al. Performance of the selfadministered psoriasis area and severity index in evaluating clinical and sociodemographic subgroups of patients with psoriasis. Arch Dermatol. 2003;139:353–8.
- Nash AS, McAteer H, Schofield J, et al. Psoriasis today: experiences of healthcare and impact on quality of life in a major UK cohort. Prim Health Care Res Dev. 2015;16:415–23.
- Strohal R, Prinz JC, Girolomoni G, et al. A patient-centred approach to biological treatment decision making for psoriasis: an expert consensus. J Eur Acad Dermatol Venereol. 2015;29:2390–8.
- Gonzalez JM, Johnson FR, McAteer H, et al. Comparing preferences for outcomes of psoriasis treatments among patients and dermatologists in the U.K.: results from a discrete-choice experiment. Br J Dermatol. 2017;176:777–85.

Affiliations

Bruce Strober^{1,2} · Peter C. M. van de Kerkhof³ · Kristina Callis Duffin⁴ · Yves Poulin⁵ · Richard B. Warren⁶ · Claudia de la Cruz⁷ · Joelle M. van der Walt⁸ · Bradley S. Stolshek⁹ · Mona L. Martin¹⁰ · Andre V. E. de Carvalho¹¹

- ¹ University of Connecticut Health Center, 21 South Road, Second Floor, Farmington, CT 06032, USA
- ² Probity Medical Research, Waterloo, ON, Canada
- ³ Radboud University Medical Center, Nijmegen, The Netherlands
- ⁴ University of Utah, Salt Lake City, UT, USA
- ⁵ Laval University and Centre de Recherche Dermatologique du Quebec Metropolitain, Quebec City, QC, Canada
- ⁶ Dermatology Centre, Salford Royal NHS Foundation Trust, Manchester NIHR Biomedical Research Centre, University of Manchester, Manchester, UK

- ⁷ Clínica Dermacross, Santiago, Chile
- ⁸ International Psoriasis Council, St. Louis, MO, USA
- ⁹ Amgen Inc., Thousand Oaks, CA, USA
- ¹⁰ Health Research Associates, Inc., Seattle, WA, USA
- ¹¹ Santa Casa de Misericórdia de Porto Alegre Hospital, Porto Alegre, Brazil