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The Development of a Patient-Reported Outcome Measure for Assessment of Genital Psoriasis Symptoms: The Genital Psoriasis Symptoms Scale (GPSS)

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ABSTRACT

Introduction: Patient-reported outcome measures (PROs) specific for genital psoriasis (GenPs) have not been described.

Methods: In this cross-sectional, qualitative study in patients with moderate-to-severe GenPs, we sought to develop a PRO useful for

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GenPs symptom assessment. A literature review was performed to identify relevant psoriasis or GenPs symptoms and existing PROs that may be useful in the evaluation of symptom severity in GenPs patients. The literature review findings were discussed with clinicians, and then patients with GenPs.

Results: Relevant psoriasis or GenPs symptoms from the literature review included itch, pain, scaling, redness/erythema, and stinging/burning. The validity of these symptoms for GenPs and potentially relevant PROs was corroborated by clinical experts. After gap analysis, a draft symptom scale consisting of Numeric Rating Scale (NRS) items was constructed. We then conducted interviews with GenPs patients ($n = 20$) to support content validity and use of the draft symptom NRS items in routine practice and in clinical trials. Participants identified and confirmed relevant symptoms and evaluated the utility of the draft PRO. A new PRO was developed: the Genital Psoriasis Symptoms Scale (GPSS). Cognitive debriefing and cultural adaptation/translation interviews with a second group of patients confirmed cultural appropriateness of the GPSS.

Conclusion: The GPSS may be useful for assessing symptoms before, during, and after treatment in routine clinical practice and in clinical trials involving patients with GenPs.

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Keywords: Genital psoriasis; Health-related quality of life; Psoriasis; Patient-reported outcomes

PLAIN LANGUAGE SUMMARY

People with psoriasis experience raised red patches of skin. The raised red patches of skin can occur anywhere on the body, including the genital area. When raised red patches of skin are on the genital area, it can be upsetting, uncomfortable, and painful. The raised red patches of skin may burn, itch, bleed, and hurt. The purpose of this research was to develop a set of questions that doctors and researchers can use to determine common symptoms experienced by patients with genital psoriasis and to measure the severity of these symptoms. On the basis of research and interviews with doctors and patients, we determined that genital psoriasis can cause itching, pain, discomfort, stinging, burning, redness, scaling, and cracking. The new questionnaire has eight questions, one for each symptom. For example, one question asks patients to rate the severity of itching from 0 (no itch) to 10 (worst itch imaginable) in their genital area. Patients can be asked to answer these questions before, during, and after treatment with different medicines. Doctors and researchers can use patients' answers to help determine how well a medicine is helping the patient.

INTRODUCTION

A substantial number (29–63%) of patients with chronic plaque psoriasis report having psoriatic lesions in the genital area at some time during the course of their disease [1–3]. Genital psoriasis (GenPs) sometimes lacks the characteristic scale present at other bodily sites because of moistness and maceration [4, 5], and fissures and erosions may be present [6, 7]. Because GenPs may not have the appearance of classic chronic plaque psoriasis, GenPs may be misidentified by the patient (e.g., as a sexually transmitted disease [2]).

In a survey of patients with GenPs ($n = 354$), 87% reported itch, and 39% reported pain [3]. After correcting for overall psoriasis severity, psoriasis patients with genital lesions report worse health-related quality of life than patients without genital involvement [3, 8]. Moreover, psoriasis patients with genital lesions report greater feelings of stigmatization and lower self-esteem than patients with lesions in visible areas [9]. There have been substantial advances in other aspects of psoriasis research, but information on the identification and treatment of GenPs in routine dermatologic practice has been sparse; patients with GenPs are often not examined or questioned for this manifestation and its psychosexual implications [10–13].

Few data exist for the efficacy of treatment for psoriasis in the genital area despite the considerable morbidity and psychosocial impact associated with this condition. Topical treatments for GenPs include steroids and vitamin D analogues [2, 10]. Systemic therapy is generally reserved for second-line treatment or more severe cases [10, 14]. Although numerous patient-reported outcome measures (PROs) are available for measuring symptoms of general psoriasis [15, 16], none specifically pertain to GenPs. In this study, we report development and content validation of a new PRO that measures symptoms specific to GenPs. The newly developed Genital Psoriasis Symptoms Scale (GPSS) may have applicability for use in clinical trials and in standard clinical practice for patients with GenPs.

METHODS

Study Objectives and Design

The purpose of this cross-sectional study was to support content validity and the use of existing or adapted PROs with GenPs patients. First, a literature review was performed to identify psoriasis- or GenPs-associated symptoms and existing PROs that could be used to assess the severity of these symptoms in patients with GenPs. The results of the literature review were confirmed by clinicians. We then performed a

gap analysis to evaluate the amount of evidence available for use of these existing PROs in patients with GenPs. The literature review results and subsequent gap analysis led to creation of the draft Symptom Numeric Rating Scale (NRS) used in the qualitative patient interviews, which were conducted using both concept elicitation and cognitive debriefing methods. The draft Symptom NRS that was used in the elicitation interviews was then modified on the basis of the patient input. Cognitive debriefing was then conducted on the final instrument using a second multinational set of patients with GenPs.

Literature Review

To identify peer-reviewed articles and PROs that were relevant to symptoms of psoriasis and GenPs, we performed a search of literature, conference proceedings, and recent clinical trials (Table S1 in the supplementary material). The search was limited to English-language publications that were published between 2005 and February 2015 and conference abstracts that were published between 2011 and February 2015; both were indexed in EMBASE/Medline. The clinical trial search was limited to future or active clinical trials listed in www.clinicaltrials.gov between 2013 and 2015.

Input from Clinicians

Two clinicians including one author (CR) of this manuscript were interviewed to confirm GenPs symptoms most relevant to patients as gleaned from the literature review and to endorse the use of specific PROs to assess these symptoms in GenPs patients. The purpose was to discuss patient symptoms and possibly relevant PROs from the perspective of clinicians with many years of experience treating patients with psoriasis and GenPs. Both clinicians specialize in dermatology, practice in the USA, have expertise in GenPs, and have experience in the conduct of clinical trials involving psoriasis patients.

Draft Symptom NRS Items

The draft Symptom NRS items (questions) were adapted from the Itch NRS [17]. The Symptom NRS items separately assess itch, pain, discomfort, and stinging/burning, each on an 11-point scale ranging from 0 (“none”) to 10 (“worst severity imaginable”) (Table 1). Participants were asked to indicate the overall severity of the symptom by circling the number that best represented the worst symptom level they had experienced in the past 24 h. Two versions were debriefed: one focused on general psoriasis symptoms, and the other focused on GenPs symptoms.

Qualitative Interviews

The site investigator and clinical personnel identified potential participants by reviewing patient charts and patient databases and by speaking to patients either during scheduled visits to their doctor or over the phone. At screening, eligible participants were adults aged at least 18 years with confirmed chronic plaque psoriasis of at least 6 months’ duration who had an affected body surface area of at least 1% and a current or recent history (within 3 months) of moderate or severe genital involvement (Patient Global Assessment score ≥ 4 on a 6-point scale from 0 to 5), as reported by the patient and confirmed by the site investigator via medical records. Completion of the patient-reported patient global assessment of symptom severity in the genital area was required as part of the screening process to allow the site to confirm current or recent severity of GenPs, either in person at a scheduled visit to their doctor’s office or by telephone. The assessment area included the penis, scrotum, and perineum for males and the labia majora, labia minora, and perineum for females. In addition, participants must have failed to respond to or been intolerant of at least one topical therapy for GenPs. Participants were recruited from five clinical sites located in Arkansas, Indiana, Michigan, and Washington. In-person or telephone interviews (one-on-one) were planned. A semistructured guide was used. The interviews, which

Table 1 Draft Symptom Numeric Rating Scale

Itch Numeric Rating Scale

1. Please rate your itching severity due to your [genital] psoriasis by circling the number that best describes your worst level of itching in the past 24 h

0	1	2	3	4	5	6	7	8	9	10
No itch										Worst itch imaginable

Pain Numeric Rating Scale

2. Please rate your pain severity due to your [genital] psoriasis by circling the number that best describes your worst level of pain in the past 24 h

0	1	2	3	4	5	6	7	8	9	10
No pain										Worst pain imaginable

Discomfort Numeric Rating Scale

3. Please rate your discomfort severity due to your [genital] psoriasis by circling the number that best describes your worst level of discomfort in the past 24 h

0	1	2	3	4	5	6	7	8	9	10
No discomfort										Worst discomfort imaginable

Stinging/Burning Numeric Rating Scale

4. Please rate your stinging/burning severity due to your [genital] psoriasis by circling the number that best describes your worst level of stinging or burning in the past 24 h

0	1	2	3	4	5	6	7	8	9	10
No stinging/ burning										Worst stinging/ burning imaginable

were conducted between August 19, 2015 and November 19, 2015, were audio-recorded, transcribed, and deidentified. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964, as revised in 2013. Informed consent for audio recording was obtained from all subjects for being included in the study, although the local institutional review board (Chesapeake IRB, Columbia, MD, USA) had determined that the study was exempt. Packets containing study materials and the informed consent form were mailed to participants before the scheduled interviews.

The interviews consisted of both concept elicitation and cognitive debriefing components. During the elicitation portion, participants discussed GenPs-associated symptoms and severity with trained interviewers; the responses were sometimes spontaneous and sometimes probed. Completion of and discussion of the draft Symptom NRS items were conducted during the cognitive debriefing portion of the interview; this included discussions of the draft, including item clarity, ease of use, mode of administration, and frequency of administration. Each interview was conducted in a single session that lasted approximately 2 h; participants were remunerated for their time.

Item Refinement

A panel of PRO and GenPs experts modified the draft Symptom NRS items on the basis of results from the content analysis and after review of transcripts from the participant interviews. Subsequently, the GPSS was finalized for routine practice and clinical trial use for evaluation of the symptoms that are most important to GenPs patients. Cognitive debriefing interviews were then conducted to confirm language comprehension and cultural appropriateness of the GPSS items.

Cognitive debriefing and cultural adaptation/translation interviews were conducted with a second group of 50 participants with self-reported GenPs ranging in age from 18 to 82 years (average 45.7 years). These participants were from seven countries and one US territory (Australia, Austria, Belgium, Canada, the Netherlands, Puerto Rico, Turkey, and USA), and 44% were male. Before the cognitive debriefing interviews, participants were asked to review the GPSS and circle any text that was difficult to comprehend. During the interviews, participants were asked to identify any circled text that they found difficult to understand and asked to explain why. The participants were then guided line-by-line through the GPSS by the interviewer and asked to paraphrase each item. If a subject had difficulty understanding any text or a concept, the interviewers attempted to determine the reason and requested suggestions for rewording the difficult text.

Data Analysis

A content analysis approach was used to analyze the qualitative data from the concept elicitation interviews, which were based on notes, transcripts, and audio recordings. ATLAS.ti version 7.5.9 (Scientific Software Development GmbH, Berlin, Germany) was used to analyze the interview transcripts. This software systematically identifies themes within qualitative data. This enabled the development of a coding dictionary, which was based on the semistructured interview guide. We also qualitatively analyzed the participant evaluations of the draft

and final items for clarity, comprehensiveness, relevance, and understandability.

Cohen's kappa (κ), which assesses the level of agreement between two measures, was used to assess concordance between the general psoriasis and the GenPs-specific Symptom NRS items. Values between 0.40 and 0.75 represent fair-to-good agreement, and values greater than 0.75 represent excellent agreement [18].

RESULTS

Literature Search, Expert Input, and Gap Analysis

Overall, the literature search yielded 260 articles or abstracts. Of these, 52 articles, 44 abstracts, and 41 clinical trials met predefined search criteria. Among the articles, the most common psoriasis or GenPs symptoms reported were itch (mentioned by 50% of examined articles), pain (46.2%), redness/erythema (40.4%), scaling (36.5%), and stinging/burning (30.8%). "Discomfort" was mentioned in nine articles (17.3%) but was not defined. Abstract results were generally consistent with those of articles. The most relevant instruments were the Itch Visual Analogue Scale and NRS, the Psoriasis Symptom Inventory (PSI), the Psoriasis Symptom Diary (PSD), and the Self-Administered Psoriasis Area and Severity Index (SAPASI).

The symptoms of itch and burning identified during the literature search were confirmed as the most relevant by clinical experts, who also confirmed that the other identified symptoms from the review were relevant and should be considered important. The clinicians reported that from their experience, itching and burning were the most bothersome symptoms for patients. Additional signs and symptoms were discomfort, described as an "uncomfortable", "dull", or "burning sensation"; pain, including dyspareunia; redness; ulceration; and erosion.

Both clinicians agreed with selection of itch, pain, discomfort, redness, stinging, and burning as GenPs-related symptoms, but they differed on the inclusion of "scaling". Additional recommended symptoms for inclusion were dyspareunia, pain on defecation, erosion/

ulceration, inflammation, bleeding, tearing, and sensitivity. Both clinicians also agreed with conducting a gap analysis on the PROs (Itch NRS, PSI, PSD, and SAPASI) identified during the literature review, but one clinician indicated that the SAPASI may be challenging for GenPs patients because of the small area of bodily involvement.

A gap analysis assessed the content validity and psychometric properties of the PROs that were identified in the literature search and the extent to which each PRO met the Food and Drug Administration evidentiary standards for clinical trial use [19]. The chosen PROs had documented evidence supporting item conceptualization history, reliability, validity, and responsiveness [17, 20–26]. According to this analysis, the PSI and PSD were the most appropriate for assessing symptom severity of psoriasis but could not be used because of limitations on their use at the time that this study was developed. The SAPASI covers a narrow range of symptoms so was not easily adapted to GenPs. On the basis of the clinician input and the gap analysis, an adapted form of the Itch NRS for psoriasis was selected for inclusion in the qualitative study to assess the relevant symptoms of GenPs (Table 1).

Participant Interviews and Development of Final PRO

Twenty-five participants were screened, and 22 met the study criteria; of these, 20 participants were interviewed because two were unavailable because of scheduling issues. Table 2 shows baseline demographics. All participants declined in-person interviews, so the interviews were conducted by telephone.

In the interviews, GenPs was defined as psoriasis occurring on the penis, scrotum, and “area between the penis and the anus” (perineum) for males and on the “outer lip” (labia majora), “inner lip” (labia minora), and “area between the vagina and the anus” (perineum) for females. Table 3 lists sample interview questions. During the interviews, all participants reported that itch and discomfort were associated with their GenPs; other symptoms,

mentioned either in spontaneous comments or after probing from the interviewer, included redness/erythema (95%; $n = 19$), stinging/burning (95%; $n = 19$), pain (85%; $n = 17$), and scaling (75%; $n = 15$). Spontaneously reported symptoms included itch (90%; $n = 18$), redness/erythema (50%; $n = 10$), stinging/burning (45%; $n = 9$), pain (40%; $n = 8$), and cracking (30%; $n = 6$). The most bothersome symptoms were itch (40%; $n = 8$), stinging/burning (40%; $n = 8$), and pain (20%; $n = 4$). Participants differentiated between “pain” and “discomfort” by taking into account that “discomfort” had both physical and emotional (anguish) connotations. Some participants described “stinging/burning” collectively, but others distinguished between the two.

The general psoriasis Symptom NRS and GenPs Symptom NRS items had fair-to-good agreement for itch ($\kappa = 0.40$), discomfort ($\kappa = 0.55$), and stinging/burning ($\kappa = 0.61$); they had excellent agreement for pain ($\kappa = 0.77$). Although participants reported that both sets of items reflected their GenPs symptoms, more participants indicated that the location-specific item (“due to your genital psoriasis”) reflected their GenPs better than the general item (“due to your psoriasis”). A 24-h recall period was considered adequate by most participants (55%; $n = 11$).

Item Refinement and Development of GPSS

On the basis of the patient interviews, the draft Symptom NRS items were modified for use in clinical trials and in clinical practice, resulting in the GPSS. The GPSS defines the genital area as “the penis, scrotum, and perineum (area between the penis and anus) for males” and as “the labia majora (outer lips), labia minora (inner lips), and perineum (area between vagina and anus) for females”. The GPSS contains eight items regarding GenPs symptoms and has a recall period of 24 h (Table 4). The items separately address itch, pain, discomfort, stinging, burning, redness, scaling, and cracking on an 11-point scale where 0 represents “no symptom” and 10 represents “worst symptom

Table 2 Patient demographics

Characteristics	Number of patients responding	<i>n</i> (%) or mean (SD)
Age, years [mean (SD)]	20	45 (14.2)
Sex, <i>n</i> (%)	20	
Female	–	11 (55)
Race, <i>n</i> (%)	20	
White	–	18 (90)
Black or African American	–	1 (5)
Multiple races	–	1 (5)
BSA score, mean (SD)	15	10.4 (12.7)
Duration of genital psoriasis, years [mean (SD)]	20	7.5 (9.7)
Duration of psoriasis, years [mean (SD)]	19	18 (14)
Sexual activity status, <i>n</i> (%)	20	–
Not active	–	9 (45)
Active	–	9 (45)
Not asked ^a	–	2 (10)
Self-reported severity of overall psoriasis symptoms (worst over past 3 months), <i>n</i> (%)	20	–
0 (clear)	–	0
1	–	1 (5)
2	–	1 (5)
3	–	5 (25)
4	–	5 (25)
5 (severe)	–	8 (40)
Self-reported severity of genital psoriasis symptoms (worst over past 3 months), <i>n</i> (%) ^b	20	–
0 (clear)	–	0
1	–	0
2	–	1 (5)
3	–	5 (25)
4	–	8 (40)
5 (severe)	–	6 (30)
Self-reported general health within past week, <i>n</i> (%)	20	–
Excellent	–	2 (10)
Very good	–	4 (20)
Good	–	11 (55)
Fair	–	3 (15)
Poor	–	0
Currently receiving treatment for overall psoriasis, <i>n</i> (%)	20	14 (70)

BSA body surface area

^a The question was not asked because of conversation flow, auditory cues, and subject's apparent lack of comfort with sensitive topics per interviewer judgment

^b All participants met eligibility criteria (Patient Global Assessment ≥ 4 , 6-point scale from 0 to 5) at time of screening; the table reflects responses at the time of the interview

Table 3 Sample interview questions**Concept elicitation: symptom experience**

What symptoms do you experience with your genital psoriasis?

How would you describe [symptom]?

How frequently do you experience [symptom]?

How severe is the [symptom]?; How long does your [symptom] typically last?

Concept elicitation: bother assessment

Thinking specifically about your genital psoriasis, which of the symptoms that we have discussed are most bothersome or affect you the most? Why?

Cognitive debriefing

What do you think about the scale? When responding to the question, what did you consider when selecting your answer?

What do you think about the instructions? Are there words in the instructions that need to be clearer?

Please look at the response options 0 [no (symptom)] to 10 [worst (symptom) imaginable]. Are you able to rate your [symptom] using these response options?

What do you think about the recall period of the questions—the past 24 h? What do you think about that amount of time?

imaginable". Each of the eight items are scored separately; in addition, a total score ranging from 0 (no GenPs symptoms) to 80 (worst imaginable GenPs symptoms) is reported. If any item score is missing, the GPSS total score will be missing.

Cognitive debriefing and cultural adaptation/translation interviews were conducted on the final version of the GPSS. In the cultural adaptation/translation component, there were no issues with the English-language version, and some minor changes were made in the Spanish and French versions. Overall, the GPSS items had confirmed clarity, comprehensiveness, relevance, and understandability.

DISCUSSION

Here we reported the development of a new PRO, the GPSS. This multiple item instrument was modeled after the Itch NRS, which contains a single item pertaining to the severity of itch during the previous 24 h [17]. The GPSS was designed to measure the severity of multiple

symptoms specific to GenPs. Whereas multiple PROs are available to measure symptoms of patients with general psoriasis, the GPSS directly addresses a specific disease manifestation of psoriasis that is particularly burdensome to patients. Patients with GenPs report substantial physical and psychosocial distress, and it has been suggested that improvements should be made in both physical and psychological support for these patients [12]. To this end, a tool that can be used to assess GenPs symptoms during treatment is needed. The GPSS has applicability to both clinical trials and routine clinical practice.

The work described here establishes content validation of the GPSS. Content validation is an initial step in the development of a new PRO, and this work was conducted in accordance with applicable guidelines and best research practices [19, 27, 28]. During the patient interviews, participants reported that the draft Symptom NRS items that specifically mentioned GenPs were more relevant to their condition. However, on the basis of patient interviews, items of the draft Symptom NRS

Table 4 Genital Psoriasis Symptoms Scale (GPSS)

Rating of severity based on your psoriasis symptoms in the genital area ^a within the past 24 h	Response options
Itching ^b	No itch (0)–worst itch imaginable (10)
Pain ^b	No pain (0)–worst pain imaginable (10)
Discomfort ^b	No discomfort (0)–worst discomfort imaginable (10)
Stinging ^b	No stinging (0)–worst stinging imaginable (10)
Burning ^b	No burning (0)–worst burning imaginable (10)
Redness ^b	No redness (0)–worst redness imaginable (10)
Scaling ^b	No scaling (0)–worst scaling imaginable (10)
Cracking ^b	No cracking (0)–worst cracking imaginable (10)

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^a *Genital area* is defined as the labia majora (outer lips), labia minora (inner lips), and perineum (area between vagina and anus) for females and the penis, scrotum, and perineum (area between the penis and anus) for males

^b Please rate your symptom severity due to your genital psoriasis by selecting the number that best describes your worst level in the past 24 h

were modified to separate stinging/burning into two items and to add redness, scaling, and cracking, leading to the final version of the GPSS. Each of the eight individual items receives a score of 0–10 and is reported as item scores for itch, pain, discomfort, stinging, burning, redness, scaling, and cracking. In addition, a total score ranging from 0 (no GenPs symptoms) to 80 (worst imaginable GenPs symptoms) is reported. The GPSS has a recall period of 24 h. The measure is culturally appropriate, easy to use and understand, and can be completed by patients either on paper or electronically. Finally, the measure is specific to GenPs and considers the symptomology of an underserved group of patients.

The definition of GenPs used here was precisely defined in both male and female patients on the basis of guidance from advisors and in consideration of the areas defined in the modified Genital Psoriasis Area and Severity Index [3, 29]. In clinical practice patients may present

with psoriasis in adjacent areas of the inguinal region and in the rima ani; however, the instrument itself clearly defines GenPs to ensure consistency when used in clinical trial settings.

This work does have a few limitations, including generalization to all patients with GenPs. Racial minorities, notably African Americans, were underrepresented during concept elicitation. The concept elicitation interviews were conducted in late summer and fall, but psoriasis flares can be seasonal [30]. Finally, the work described here is only qualitative, so the psychometric properties of the GPSS must still be evaluated to determine its validity, reliability, and ability to measure changes of psoriasis symptoms.

CONCLUSIONS

The GPSS provides a means for patients to communicate GenPs symptoms in a manner

that is less personally invasive than in-person discussions by using paper or an electronic device. As such, the GPSS may help solicit information relevant to the understanding of the burden of GenPs on individuals, and its use can facilitate discussion with patients and garner information needed to make treatment decisions and to monitor the success of treatment in both clinical trials and routine practice.

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Compliance with Ethics Guidelines. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964, as revised in 2013. Informed consent for audio recording was obtained from all subjects for being included in the study, although the local institutional review board (Chesapeake IRB, Columbia, MD) had determined that the study was exempt.

Data Availability. The datasets generated during and/or analyzed during the current study are in the form of audio recordings and transcripts, and are not publicly available because of patient privacy.

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