

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

Gottlieb AB, Kirby B, Ryan C, Naegeli AN, Burge R, Potts Bleakman A, Anatchkova MD, Yosipovitch G. *Dermatol Ther (Heidelb)*. 2017.

This slide deck represents the opinions of the authors. Sponsorship for this study was funded by **Eli Lilly and Company**. Medical writing assistance for this study was provided by **Lori Kornberg, PhD (INC Research)**. For a full list of acknowledgments and conflicts of interest for all authors of this article, please see the full text online. Copyright © The Authors **2017**. Creative Commons Attribution Noncommercial License (CC BY-NC).

Abbreviations

- BSA: body surface area
- GenPs: genital psoriasis
- HRQoL: health-related quality of life
- NRS: Numeric Rating Scale
- GPSS: Genital Psoriasis Symptoms Scale
- PRO: patient-reported outcome
- SD: standard deviation

Introduction

- Up to 63% of patients with chronic plaque psoriasis have psoriatic lesions in the genital area at some point during the course of their disease¹⁻³
- In a survey of patients with GenPs (n = 354), 87% reported itch and 39% reported pain³
- Psoriasis patients with genital lesions report worse HRQoL than patients without genital involvement^{3,4} and greater feelings of stigmatization and lower self-esteem than patients with lesions in visible areas⁵
- Although PROs are available for measuring symptoms of general psoriasis,^{6,7} none specifically pertain to GenPs
- The purpose of this cross-sectional study is to report the development and content validation of a new PRO, the GPSS, that measures symptoms specific to GenPs

Methods

- Literature review
 - English-language publications from 2005-2015 and conference abstracts published from 2011-2015
- Clinician input
 - Two USA-based dermatologists (including one author of this manuscript)
- Draft Symptom NRS questions based on Itch NRS
 - Separately assess itch, pain, discomfort, stinging/burning (11-point scale)
- Concept elicitation interviews with adult GenPs patients
 - Confirmed chronic plaque psoriasis ≥ 6 months with affected BSA $\geq 1\%$
 - Current or recent history of moderate or severe genital involvement
 - Failed to respond to or intolerant of ≥ 1 topical therapies for GenPs
- Item refinement followed by cognitive debriefing interviews
 - Second set of participants from 7 countries interviewed to confirm item comprehension and cultural appropriateness of final GPSS items

Results: Literature Review

- 52 articles, 44 abstracts, and 41 clinical trials met predefined search criteria
- Most common psoriasis or GenPs symptoms reported:
 - Itch (50%)
 - Pain (46.2%)
 - Redness/erythema (40.4%)
 - Scaling (36.5%)
 - Stinging/burning (30.8%)
 - “Discomfort” was mentioned in 9 articles (17.3%) but was not defined
- Abstract results were generally consistent with those of articles

Results: Clinician Input

- Identified itch and burning as most relevant symptoms
 - Reported as the most bothersome for patients
- Confirmed other symptoms from literature review were relevant
 - Differed on inclusion of scaling
- Additional recommendations for inclusion:
 - Dyspareunia, pain on defecation, erosion/ulceration, inflammation, bleeding, tearing, sensitivity
- Subsequent gap analysis assessed content validity and psychometric properties of the PRO measures identified in the literature
- Based on clinician input and 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

Results: Concept Elicitation Interviews - Patient Demographics (1 of 2)

Characteristics	Number of patients responding	<i>n</i> (%) or mean (SD)
Age, years [mean (SD)]	20	45 (14.2)
Sex, female [<i>n</i> (%)]	20	11 (55)
Race [<i>n</i> (%)]	20	-
White	-	18 (90)
Black or African American	-	1 (5)
Two or more races	-	1 (5)
Duration of psoriasis, years [mean (SD)]	19	18 (14)
Duration of genital psoriasis, years [mean (SD)]	20	7.5 (9.7)
BSA score [mean (SD)]	15	10.4 (12.7)
Currently receiving treatment for overall psoriasis [<i>n</i> (%)]	20	14 (70)

Results: Concept Elicitation Interviews - Patient Demographics (2 of 2)

Characteristics	Number of patients responding	<i>n</i> (%) or mean (SD)
Self-reported severity of genital psoriasis symptoms (worst over past 3 months) [<i>n</i> (%)] ^a	20	-
0 (clear)	-	0
1	-	0
2	-	1 (5)
3	-	5 (25)
4	-	8 (40)
5 (severe)	-	6 (30)
Sexual activity status [<i>n</i> (%)]	20	-
Not active	-	9 (45)
Active	-	9 (45)
Not asked ^b	-	2 (10)

^aAll 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

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

Results: Concept Elicitation Interviews

- All participants declined in-person interviews; interviews were conducted by telephone
- Concepts mentioned spontaneously
 - Itch (90%, $n = 18$)
 - Redness/erythema (50%, $n = 10$)
 - Stinging/burning (45%, $n = 9$)
 - Pain (40%, $n = 8$)
 - Cracking (30%, $n = 6$)
- Most bothersome symptoms
 - Itch (40%, $n = 8$)
 - Stinging/burning (40%, $n = 8$)
 - Pain (20%, $n = 4$)

Genital Psoriasis Symptoms Scale

Rating of severity based on your psoriasis symptoms in the genital area^a within the past 24 hours^b

Response options

Itching	No itch (0) - worst itch imaginable (10)
Pain	No pain (0) - worst pain imaginable (10)
Discomfort	No discomfort (0) - worst discomfort imaginable (10)
Stinging	No stinging (0) - worst stinging imaginable (10)
Burning	No burning (0) - worst burning imaginable (10)
Redness	No redness (0) - worst redness imaginable (10)
Scaling	No scaling (0) - worst scaling imaginable (10)
Cracking	No cracking (0) - worst cracking imaginable (10)

^aGenital 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

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

Cognitive Debriefing Interviews

- Conducted with a second set of participants in 7 countries (N=50)
 - Mean age: 45.7 years (range 18-82 years)
 - Male: 44%
- In the cultural adaptation/translation component:
 - There were no issues with the English-language version
 - Some minor changes were made in the Spanish and French versions
- Overall, the GPSS items had confirmed clarity, comprehensiveness, relevance, and understandability

Discussion

- We reported the development of a new PRO, the GPSS, designed to measure the severity of multiple symptoms specific to GenPs
 - Modeled on Itch NRS, a single-item tool pertaining to psoriasis itch severity
- This work establishes content validation of the GPSS
- The GPSS is culturally appropriate, is easy to use and understand, and can be completed on paper or electronically
- Limitations:
 - Generalization to all patients with GenPs
 - Racial minorities, notably African Americans, were underrepresented during concept elicitation
 - Concept elicitation interviews were conducted in late summer and fall, but psoriasis flares can be seasonal
 - This work is qualitative; psychometric properties of the GPSS must be evaluated to determine validity, reliability, and ability to measure symptom changes

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

Acknowledgments

Funding

This study was funded by Eli Lilly and Company, Indianapolis, Indiana, USA, which contracted with Evidera (Bethesda, Maryland) for the design and analysis of the study. Article processing charges were funded by Eli Lilly and Company, Indianapolis, IN, USA. All authors had full access to all of the data in this study and take complete responsibility for the integrity of the data and accuracy of the data analysis.

Authorship

All named authors meet the International Committee of Medical Journal Editors criteria for authorship for this manuscript, take responsibility for the integrity of the work as a whole, and have given final approval for this version to be published.

Medical Writing and/or Editorial Assistance

Writing and editorial assistance in the preparation of this manuscript were provided by Lori Kornberg, PhD (INC Research, Raleigh, NC), Meredith Fraser, MFA (INC Research, Raleigh, NC), and Kristin Hollister, PhD (Eli Lilly and Company, Indianapolis, IN). Support for this assistance was funded by Eli Lilly and Company. The authors would like to thank the participants who shared the personal details of their genital psoriasis.

Disclosures

A. Gottlieb is a consultant and advisory board member for Janssen, Celgene, Bristol Myers Squibb, Beiersdorf, AbbVie, UCB, Novartis, Incyte, Eli Lilly and Company, Dr Reddy's Laboratories, Valeant, Dermira, Allergan, and Sun Pharmaceutical Industries. She received research and educational grants from Janssen and Incyte.

B. Kirby receives research grants from AbbVie, Novartis, Merck-Sharpe-Dolme, and Pfizer. He has acted as a consultant and/or speaker for AbbVie, Novartis, Janssen, Celgene, Almirall, Eli Lilly and Company, and LEO Pharma.

C. Ryan has acted as an advisor and/or speaker for AbbVie, Aqua, Dermira, Dr Reddy's Laboratories, Eli Lilly and Company, Janssen, Medimetrix, Novartis, Regeneron-Sanofi, UCB, and XenoPort.

M. Anatchkova is an employee of Evidera. Evidera received research study support from Eli Lilly and Company.

G. Yosipovitch is a consultant and advisory board member for Eli Lilly and Company, Opko, Menlo, Trevi, Regeneron, Sanofi, Sienna, and Novartis. He receives research support from the LEO Foundation, GlaxoSmithKline, Pfizer, and Allergan.

A. N. Naegeli is a full-time employee of Eli Lilly and Company and owns stock.

A. Potts Bleakman is a full-time employee of Eli Lilly and Company and owns stock.

R. Burge is a full-time employee of Eli Lilly and Company and owns stock.

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.

Copyright

Copyright © The Authors 2017.

This slide deck is distributed under the terms of the Creative Commons Attribution Noncommercial License which permits any noncommercial use, distribution, and reproduction in any medium, provided the original author(s) and the source are credited.