

The Development of the Genital Psoriasis Sexual Frequency Questionnaire (GenPs-SFQ) to Assess the Impact of Genital Psoriasis on Sexual Health

Gottlieb AB, Kirby B, Ryan C, Naegeli AN, Burge R, Potts Bleakman A, Anatchkova MD, Cather J. *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
- GenPs-SFQ: Genital Psoriasis Sexual Frequency Questionnaire
- HCP: health care provider
- HRQoL: health-related quality of life
- 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
- GenPs has a significant impact on sexual health³⁻⁶
- Although PROs are available for measuring symptoms and the impact of overall psoriasis on HRQoL, none are specific to GenPs
- The purpose of this cross-sectional study is to report the development and content validation of a PRO that measures the impact of GenPs on sexual health

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)
- 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 generation
 - Based on literature review, clinician input, and concept elicitation interviews
- Cognitive debriefing interviews
 - Second set of participants from 7 countries interviewed to confirm item comprehension and cultural appropriateness of final GenPs-SFQ

Results: Literature Review

- 52 articles, 44 abstracts, and 41 clinical trials met predefined search criteria
- Most frequent concepts mentioned overall:
 - Psychological feelings ($n = 42$, 80.8%)
 - Social relationships ($n = 37$, 71.2%)
 - Physical activities or general physical functioning ($n = 31$, 59.6%)
 - Daily living and activities ($n = 29$, 55.8%)
 - General HRQoL ($n = 29$, 55.8%)
- Sexual functioning was discussed by 19 (36.5%) reviewed articles
 - 3 (5.8%) discussed this concept in relation to GenPs
- Most frequent concepts on further targeted search of sexual function:
 - Dyspareunia ($n = 2$, 4.5%)
 - Increased discomfort or worsening of symptoms after sex ($n = 2$, 4.5%)
 - Sexual dysfunction ($n = 2$, 4.5%)

Results: Clinician Input

- Sexual function (which encompasses sexual activity) was identified as the most relevant functional impact of GenPs
- Specific impacts on sexual activity included:
 - Fear of and avoidance of sex
 - Pain during sexual intercourse
 - Worsening of psoriasis after intercourse
 - Bleeding and cracking in the genital area

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: Functional Impact Concepts From Patient Interviews

- All participants declined in-person interviews; interviews were conducted by telephone

| Sexual impact concepts | Frequency of mention, <i>n</i> (%) | | |
|---|------------------------------------|-------------|---------------|
| | Total | Spontaneous | After probing |
| Decreased sexual frequency | 16 (80) | 7 (35) | 9 (45) |
| Worsening of genital psoriasis symptoms after sexual activity | 16 (80) | 12 (60) | 4 (20) |
| Negative effects on sexual experience | 16 (80) | 13 (65) | 3 (15) |
| Avoidance of sexual relationships | 15 (75) | 12 (60) | 3 (15) |
| Reduced sexual desire | 11 (55) | 2 (10) | 9 (45) |

Genital Psoriasis Sexual Frequency Questionnaire

Please answer the questions based on your psoriasis symptoms in the genital area^a within the past week

In the past week, how many times did you engage in sexual activity?^b

Response options

Score

Two or more

0

Once

1

None / zero

2

In the past week, how often did your genital psoriasis limit the frequency of your sexual activity?^b

Never

0

Rarely

1

Sometimes

2

Often

3

Always

4

Higher scores indicate less sexual frequency...

...and more limitations on sexual frequency due to genital psoriasis

^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

^bNot limited to sexual intercourse and includes activities such as masturbation

Cognitive Debriefing Interviews

- Conducted with a second set of participants in 7 countries (N=50)
 - Mean age: 47.5 ± 14.6 years (range 18-82 years)
 - Mean academic education: 13 ± 3.8 years (range 6-23 years)
- Based on participant input:
 - No reported difficulty interpreting or using the GenPs-SFQ items
 - Instructions and items adequately capture concepts as intended
 - Was easily understood in English and other languages
 - Confirmed as culturally appropriate
 - Recall period of 1 week was appropriate, made sense, and was relevant
 - Participants reported no difficulty remembering their experiences over this period

Discussion

- GenPs-SFQ was developed specifically for individuals with GenPs
- GenPs-SFQ quantifies the impact of GenPs on patients' sexual activity in terms of decrease in sexual frequency
- These items are easy to understand and can be administered either on paper or electronically
- The work described here establishes content validity
- Limitations:
 - The extent to which these findings can be generalized to all GenPs patients; however, saturation was reached with 20 patients
 - Racial minorities were underrepresented in the original sample
 - Sexual orientation was not included in baseline demographic questions
 - This work is qualitative; psychometric properties of the GenPs-SFQ need to be evaluated to determine reliability

Conclusion

- The GenPs-SFQ may help obtain information that is relevant to understanding the burden of GenPs and inform potential treatment in both clinical and research settings

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 (ICMJE) criteria for authorship for this manuscript, take responsibility for the integrity of the work as a whole, and have given final approval to the 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, Medimetriks, Novartis, Regeneron-Sanofi, UCB, and XenoPort.

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

J. Cather is in the speaker bureaus of AbbVie, Celgene, Eli Lilly and Company, and Janssen; received honoraria from AbbVie, Eli Lilly and Company, Janssen, and Novartis; is a consultant for AbbVie, Actelion, Eli Lilly and Company, and Janssen; is an investigator for Celgene, Cutanea, Dermira, GaldermaLabs, GlaxoSmithKline, Janssen, Merck, Novartis, Pfizer, Regeneron, Sandoz, TolmarPharma, Vitae, and Xenoport; has received grants from Allergan, Celgene, Cutanea, Dermira, GlaxoSmithKline, GaldermaLabs, Janssen, MSD, Novartis, Pfizer, Regeneron, Sandoz, TolmarPharma, Vitae, and XenoPort; and has received other financial benefit from AbbVie.

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. Written and verbal informed consent for audio recording was obtained from all participants for being included in the study, although the study was determined to be "exempt" by the local IRB (Chesapeake IRB, Columbia, MD).

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.