The Treatment of Genital Psoriasis

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- Research support and/or consultant and/or lecturer for AbbVie, Afecta, Amgen, Inc., Avillon, Boehringer-Ingelheim, Celgene, Dermira, Eli Lilly, Galderma, Janssen Biotech, Inc., LEO Pharma, Menlo, Novartis, OrthoDermatologics, Pfizer, Procter & Gamble, Promius, Regeneron, and Sun Pharmaceuticals

- No stock ownership or Board membership on any Pharmaceutical or Biotechnology company
Clinical presentation of genital psoriasis may differ from that of extra-genital plaque psoriasis

- *Due to moisture and maceration, genital psoriasis lesions lack the characteristic scale present at other body sites*\(^1,2\)

Genital psoriasis symptoms impact quality of life differently than psoriasis on other body locations

- *Itch and sexual impairment are among the most commonly reported symptoms in patients with genital psoriasis*\(^3,4\)
- *Significant quality of life issues vs. patients without genital involvement, as measured by quality of life scales including DLQI*\(^3,4\)

Need for Genital Psoriasis Outcome Measures (2)

- No measures have been regularly used in clinical trials or clinical practice to assess severity of genital psoriasis

- An abundance of patient-reported outcomes assessing HRQoL for general psoriasis exist; however, none specifically focus on symptoms or impact of genital psoriasis
Specific Outcome Measures

- **Clinician-Rated Assessments of Severity of Genital Psoriasis**
  - Static Physician Global Assessment (sPGA) of Genitalia
  - Modified Genital Psoriasis Area and Severity Index (mGPASI)

- **Combined Clinician/Patient-Reported Assessment of Genital Psoriasis**
  - Comprehensive Assessment of the Psoriasis Patient (CAPP) – Genital Sub-index

- **Patient-Reported Outcome Measures of Genital Psoriasis**
  - Genital Psoriasis Symptoms Scale (GPSS)
  - Sexual Frequency Questionnaire (SFQ)
  - Genital Psoriasis Sexual Impact Scale (GPSIS)

- **Patient-Reported Outcome Measures not Specific to Genital Psoriasis**
  - Touch Avoidance Numeric Rating Scale (TA-NRS)
Traditional sPGA ratings weight erythema, induration, and scaling equally

The sPGA of Genitalia is a modified version of the sPGA
  • Designed to specifically evaluate plaque lesion severity in the genital area rather than the entire body
  • Due to the importance of erythema in genital psoriasis presentation, erythema is the dominant feature influencing the sPGA of Genitalia rating

Developed with input from an Expert Consensus Development panel and clinical experts in genital psoriasis
Static Physician Global Assessment (sPGA) of Genitalia

- Measurement of the patient’s psoriasis severity in the genital region at a given time point on a 6-point scale
  - Labia majora, labia minora, and perineum in females
  - Penis, scrotum, and perineum in males

0- Clear
1- Minimal
2- Mild
3- Moderate
4- Severe
5- Very Severe
<table>
<thead>
<tr>
<th>Score</th>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
</table>
| 0     | Clear      | Erythema = 0 (residual post-inflammatory hyperpigmentation or hypopigmentation may be present)  
Plaque elevation = 0 (no elevation)  
Scaling = 0 (no scale) |
| 1     | Minimal    | Erythema = faint (light pink coloration)  
Plaque elevation = ± (slight but not definitive elevation)  
Scaling = ± (surface dryness with some white coloration) |
| 2     | Mild       | Erythema = mild (pink to light red coloration)  
Plaque elevation = slight (slight but definitive elevation)  
Scaling = fine (fine scale partially or mostly covering lesions) |
| 3     | Moderate   | Erythema = moderate (definite red coloration)  
Plaque elevation = moderate (with rough or sloped edges)  
Scaling = coarser (coarse scale covering most of the lesions) |
| 4     | Severe     | Erythema = severe (bright red coloration)  
Plaque elevation = marked (with hard or sharp edges)  
Scaling = coarse (coarse, non-tenacious scale covering most lesions) |
| 5     | Very severe| Erythema = very severe (extreme red coloration)  
Plaque elevation = very marked (with hard sharp edges)  
Scaling = very coarse (coarse, thick tenacious scale over most lesions) |
Perivaginal area from clitoral prepuce to perineum including labia minora and majora

Female sPGA of Genitalia: region to be assessed
Area includes penis, scrotum and perineum
Varying Clinical Degrees of Erythema Reviewed, Females

0 - Nil
1 - Minimal
2 - Mild
Varying Clinical Degrees of Erythema Reviewed, Females

3- Moderate
4- Severe
5- Very Severe
Varying Clinical Degrees of Erythema Reviewed, Males (1)

0- Nil

1- Minimal

2- Mild
Varying Clinical Degrees of Erythema Reviewed, Males

3- Moderate

4- Severe

5- Very Severe
Patient-reported assessment of 8 psoriasis symptoms in the genital area

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Severity Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Itch</td>
<td>0-10</td>
</tr>
<tr>
<td>Pain</td>
<td>0-10</td>
</tr>
<tr>
<td>Discomfort</td>
<td>0-10</td>
</tr>
<tr>
<td>Stinging</td>
<td>0-10</td>
</tr>
<tr>
<td>Burning</td>
<td>0-10</td>
</tr>
<tr>
<td>Redness</td>
<td>0-10</td>
</tr>
<tr>
<td>Scaling</td>
<td>0-10</td>
</tr>
<tr>
<td>Cracking</td>
<td>0-10</td>
</tr>
</tbody>
</table>

- Individual symptom severity is indicated by selecting the number from 0 (no symptoms) to 10 (worst symptoms imaginable) that best describes the worst level of symptom severity in the genital area in the past 24 hours.

- A total score ranging from 0 (no genital psoriasis symptoms) to 80 (worst imaginable genital psoriasis symptoms) is determined by the sum of the individual symptom scores.

- Developed by Eli Lilly

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*Genital area is defined as the labia majora, labia minora, and perineum for females; penis, scrotum, and perineum for males. NRS=Numeric Rating Scale.*
The individual item scores of the SFQ are reported separately; no total score is calculated for the SFQ. Higher scores indicate less sexual frequency and more limitations on sexual frequency due to genital psoriasis.

<table>
<thead>
<tr>
<th>SFQ Item</th>
<th>Question</th>
<th>Response Options</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item 1:</td>
<td>In the past week, how many times did you engage in sexual activity?</td>
<td>Two or more</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Once</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Zero</td>
<td>2</td>
</tr>
<tr>
<td>Item 2:</td>
<td>In the past week, how often did your genital psoriasis limit the frequency of your sexual activity?</td>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rarely</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sometimes</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Often</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Always</td>
<td>4</td>
</tr>
</tbody>
</table>
1) Protection is KEY i.e. reduction of friction:

- Clothing should be loose-fitting and unrestricted
- Gentle, non-soap cleansers for bathing
- Always use lubricant or lubricated condom with any sexual activity
2) Specific topical agents

• Non-steroidal agents
  - Tacrolimus (Protopic®)
  - Pimecrolimus (Elidel®)

• Vitamin D Preparations

• Steroidal agents
  - Ointments preferable
  - How potent can we go?
Systemic Therapies for Genital Psoriasis

- Traditional Systemic Agents
  - Methotrexate
  - Cyclosporine
  - Retinoids
  - Apremilast
  - NO quality trials have been performed

- Biologic agents
  - To date, only Ixekizumab has been studied for genital psoriasis
Ixekizumab Treatment for Genital Psoriasis
(1)

**Trial:**
- 12-week, double blind trial (149 patients)
- All non-responders to topical treatments
- Primary endpoint (sPGA) of 0 or 1 (clear or almost clear)

**Results:**
- At week 12:
  - Ixekizumab response rate = 73%
  - Placebo = 8%
Results (continued):

Sexual Frequency Questionnaire (SFQ)
• 78% of patients on Ixekizumab group stated “never” or “rarely” versus 21% of controls

Genital Itch Numeric Rating Scale (0-10)
• 60% of Ixekizumab group with greater than 3-point improvement versus 8% of controls

- SIGNIFICANT differences apparent at week 2
Thank you for your attendance!

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