Why Assess and Quantitate the Extent of both Psoriasis and Psoriatic Arthritis in Clinic?

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Disclosure of Relevant Relationships with Industry

Current Consulting/Advisory Board Agreements:

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Research/Educational Grants (paid to Tufts Medical Center) until 5/11/16 Then None:

Centocor (Janssen), Amgen, Abbott (Abbvie), Novartis, Celgene, Pfizer, Lilly, Levia, Merck, Xenoport, Dermira, Baxalta
Reasons

• Improves communication with patients
• Helpful for prior authorizations
• Useful for quantitating case mix
• PQRS reporting
• Registries (DataDerm)
• Demonstration of excellent clinical outcomes may be a defense against physician tiering and tight networks

• It is an essential component for Treating-to-Target strategies for psoriasis management
• Early detection of PSA prevents disability
• Useful for clinical research
Improves Communications with Patients

- I teach my patients what BSA and PGA mean
- At each visit, I show them how much they have improved or I demonstrate that they have not improved enough and we need to switch treatment
- They understand my reasoning better because they understand how I measure their disease
- Quality of life is discussed on a more subjective level because we have no clinically practical dermatology quality of life measurement
Helpful for Interactions with Payers and Government

• Helpful for prior authorizations
• Useful for quantitating case mix
• PQRS reporting
• Registries (DataDerm)
• Demonstration of excellent clinical outcomes may be a defense against physician tiering and tight networks
Thank You to Our Corporate Members and Supporters!

Michael Klein

Susan and Ken Fahrenholtz

American Academy of Dermatology
IDEOM: Mission

• “To establish patient-centered measurements to enhance research and treatment for those with dermatologic disease”
• Perspectives of patients, health economists, payers, physicians and regulatory agencies are included from the onset
• IDEOM’s goal is to establish validated and standardized outcome measures that satisfy the needs of all stakeholders and can be applied to clinical research and clinical practice

http://dermoutcomes.org/
What Payers Need from Outcome Measures

- **Universally** accepted, published outcome measures, useful in clinical practice, and mandated to perform in published guidelines issued by major professional societies.
- **Clinically meaningful** outcome measures (i.e., not enough to be better than placebo)
  - Outcomes which can be used to justify cost given the benefit/risk aspects of a drug
  - Outcomes which can measure how the overall cost of care decreases by the treatment intervention
    - e.g., Reduce incidence of PSA or cardiovascular morbidity/mortality
- **Outcomes which measure effects on patient productivity**
- **Outcomes which, when applied universally, reduce variability in practice, thus making costs more predictable**
- **Would like to see a measure which “would look like a diagnostic test” so that a solid connection between using the outcome measure and making a therapeutic decision can be made**
  - Treat to Target is an example
- EMRs are obstacles currently
Treating to Target in PsA
PsA: Minimal Disease Activity Criteria (MDA) (GRAPPA)

- A patient is classified as in MDA when they meet 5 of 7 of the following criteria:
  - Tender joint count ≤ 1
  - Swollen joint count ≤ 1
  - PASI ≤ 1 or BSA ≤ 3
  - Patient pain VAS ≤ 15
  - Patient global activity VAS ≤ 20
  - HAQ ≤ 0.5
  - Tender enthesal points ≤ 1


PASI: Psoriatic Activity and Severity Index
BSA: body surface area
VAS: visual analogue score
The TICOPA Study

Aim

- Does treat to target using MDA criteria improve outcome in psoriatic arthritis?

Primary Outcome

- ACR20 at 48 weeks

Sample Size Calculation

- 50% ACR20 response with standard care
- 70% ACR20 response with tight control
- Sample size = 186, alpha = 0.05, beta = 0.8

Primary Outcome – Complete Case Analysis

PASI Outcomes

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>OR</th>
<th>Lower 95% CI</th>
<th>Upper 95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PASI75</td>
<td>1.51</td>
<td>5.65</td>
<td></td>
<td>0.0015</td>
</tr>
</tbody>
</table>

Tight Control: 72% PASI50, 59% PASI75, 40% PASI90
 Standard Care: 52% PASI50, 33% PASI75, 20% PASI90

N=156

Prescribed Therapy at 48 Weeks

## Serious Adverse Events

<table>
<thead>
<tr>
<th></th>
<th>Tight Control</th>
<th>Standard Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>SAE</td>
<td>25</td>
<td>8</td>
</tr>
<tr>
<td>SAE related to drug</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>Blood/lymph system</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Cardiac</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>GI</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Hepatobiliary</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Immune system</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Infection/infestation</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Injury/poisoning</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>MSK and CTD</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Neoplasms</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Nervous system</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Renal/urinary</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Reproductive/breast</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Respiratory and thoracic</td>
<td>4</td>
<td>0</td>
</tr>
</tbody>
</table>

Measuring Outcomes in Clinic Allows for Clinical Research in the Practice Setting
Clinical Research: Peer Reviewed Publications Based upon PGA x BSA as the Primary Outcome Measure from My Practice


## Practical PSO/PSA Outcomes

### Tools to be Discussed Today

<table>
<thead>
<tr>
<th>Psoriasis</th>
<th>Psoriatic Arthritis</th>
<th>Quality of Life</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PGA</td>
<td>CASPAR (for diagnosis only)</td>
<td>There are none that are practical in clinic</td>
</tr>
<tr>
<td>BSA</td>
<td>PSA acronym (for diagnosis only)</td>
<td>DLQI used extensively in clinical trials</td>
</tr>
<tr>
<td>PGA x BSA aka S-MAPA</td>
<td>Visual Analog Pain scale</td>
<td></td>
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<tr>
<td></td>
<td>There are no clinically useful tools for the signs of PSA</td>
<td></td>
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</tbody>
</table>

PGA: physician global assessment; BSA: body surface area  
S-MAPA: simple measure for assessing psoriasis activity  
CASPAR: classification criteria for psoriatic arthritis  
DLQI: dermatology life quality index
We Do Not Have Any Clinically Practical Outcome Tools For:

- Signs of Psoriatic Arthritis
- Signs of Enthesitis
- Signs of Dactylitis
- Nail Psoriasis
- Genital and Intertriginous Psoriasis (Dr. Merola is working on this)
- Dermatology Quality of Life