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AN ANTI-INFLAMMATORY/ANTI-FUNGAL, NON-CORTICOSTEROID COMBINATION CREAM FOR THE TREATMENT OF MILD/MODERATE SEBORRHEIC DERMATITIS OF THE FACE: A PILOT OPEN-LABEL TRIAL UTILIZING CLINICAL AND ERYTHEMA-DIRECTED DIGITAL PHOTOGRAPHY EVALUATION

Giuseppe Micali MD, Federica Dall’Oglio MD PhD, Aurora Tedeschi MD PhD, Carmelinda Fusto MD, Francesco Lacarrubba MD

Dermatology Clinic, University of Catania, Italy

DISCLOSURE OF COMMERCIAL SUPPORT
The authors don’t have any relevant financial relationships with any commercial interests.
BACKGROUND

• **Topical agents** are generally useful in the management of facial seborrheic dermatitis (SD) by reducing inflammation and scale production (1-2)

• **Digital photography** equipped with a technology that enables separation of the unique color signatures of red skin components (3) is a useful tool for evaluation of erythema in patients affected by inflammatory dermatoses including SD


2. Elewski B. *An investigator-blind, randomized, 4-week, parallel-group, multicenter pilot study to compare the safety and efficacy of a nonsteroidal cream (Promiseb Topical Cream) and desonide cream 0.05% in the twice daily treatment of mild to moderate seborrheic dermatitis of the face.* Clin Dermatol 2009;27(6 Suppl):S48-53

CLINICAL TRIAL

• Open label not-blinded, prospective, intra-patient controlled (target area) trial

• Aim: to assess efficacy and tolerability of a non-steroid, antinflammatory/antifungal cream containing 1.2% bisabolol, 1% piroctone olamine, 1% alglycera and 0.01% telmesteine in the treatment of facial SD using clinical evaluation, erythema-directed digital photography, subject self-assessment and Physician Global Assessment (PGA)
METHODOLOGY (I)

- **N. of patients**: 20 (14M/6F; mean age 30.7 years, range 21-70)
- **Inclusion criteria**: age: >18 yrs, mild to moderate inflamed face SD; 2-week wash out from topical antimycotics/corticosteroids; 1-month wash out from oral antimycotics/corticosteroids and hormonal therapy
- **Exclusion criteria**: sun exposure; pregnancy

- Patients were instructed to apply the study cream *twice daily*, initially on a *selected target area* (approximately 10 cm²) only for 1 week
- If the subject developed *visible improvement*, it was advised to extend the application to all facial affected area for 3 additional weeks
METHODOLOGY (II)

• **Efficacy** was evaluated by measuring at baseline, week 1 and 4:
  
  ✓ **desquamation** (by clinical examination using a 4-point scale: 0=none; 1=slight; 2=mild; 3=severe)
  
  ✓ **erythema** [by digital photography (VISIA Complexion Analysis System, Canfield, Fairfield, NJ) equipped with RBX™ (Red/Brown/X) technology using a 4-point scale: 0=none; 1=slight; 3=moderate; 4=severe]
  
  ✓ **pruritus** (by subject-completed Visual Analogue Scale: 0 mm=no pruritus; 100 mm=severe pruritus)
  
• **PGA** was assessed using a 6-point scale: complete response (> 90% improvement); excellent response (70-90% improvement); moderate response (40-60% improvement); mild response (<40% improvement); no response (no change); worsening
METHODOLOGY (III)

- **Evaluation of tolerability** was assessed by a 4-point scale: excellent, good, poor, very poor
- **Cosmetic acceptability** was evaluated at week 4 by a 3-point scale: excellent, good, poor
- Data were analyzed using Kruskal-Wallis, non-parametric analysis of variance test
RESULTS (I)

- **18 subjects** completed the first week of treatment (target areas), whereas 2 were lost at follow-up (burning and personal reasons respectively)

- A **significant reduction** in erythema was observed in all patients

<table>
<thead>
<tr>
<th></th>
<th>Week 1 (median values*)</th>
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<tbody>
<tr>
<td>Desquamation</td>
<td>from 2 at baseline to 1 (n.s.)^</td>
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<tr>
<td>Erythema</td>
<td>from 2 at baseline to 1.5 (p=0.002)</td>
</tr>
<tr>
<td>Pruritus (VAS)</td>
<td>from 25 mm at baseline to 20 mm (n.s.)^</td>
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*median values = numerical values separating the higher half of a data sample, a population, or a probability distribution, from the lower half
^ n.s. = not significant
### RESULTS (II)

- All 18 subjects completed the 3 additional weeks of treatment.
- At week 4, a **significant improvement** was recorded for desquamation, erythema and pruritus.

<table>
<thead>
<tr>
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<th>Week 4 (median values*)</th>
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<tbody>
<tr>
<td><strong>Desquamation</strong></td>
<td>from 2 at baseline to 0 ((p=0.0002))</td>
</tr>
<tr>
<td><strong>Erythema</strong></td>
<td>from 2 at baseline to 1 ((p&lt;0.0001))</td>
</tr>
<tr>
<td><strong>Pruritus (VAS)</strong></td>
<td>from 25 mm at baseline to 0 mm ((p&lt;0.0001))</td>
</tr>
</tbody>
</table>

*median values = numerical values separating the higher half of a data sample, a population, or a probability distribution, from the lower half*
Baseline

Week 4: complete response
Digital photography (VISIA®): red areas (RBX™)

Baseline

Week 4: complete response
Digital photography (VISIA®): standard light

Baseline                                                                   Week 4: complete response
Digital photography (VISIA®): red areas (RBX™)

Baseline

Week 4: complete response
### RESULTS (III)

- PGA showed **improvement in 89% of patients, with a complete response in 50% of cases**
- Cosmetic acceptability and tolerability were excellent

<table>
<thead>
<tr>
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<th>Week 4</th>
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<tbody>
<tr>
<td><strong>PGA</strong></td>
<td>Complete response = 50% (9 cases)</td>
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<tr>
<td></td>
<td>Excellent response = 11% (2 cases)</td>
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<tr>
<td></td>
<td>Moderate response = 17% (3 cases)</td>
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<tr>
<td></td>
<td>Mild response = 11% (2 cases)</td>
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<tr>
<td></td>
<td>No change = 11% (2 cases)</td>
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<tr>
<td><strong>Tolerability</strong></td>
<td>Excellent = 100% (no signs of local intolerance)</td>
</tr>
<tr>
<td><strong>Cosmetic acceptability</strong></td>
<td>Excellent = 83%</td>
</tr>
<tr>
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<td>Good = 17%</td>
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</table>
DISCUSSION

• These preliminary results indicate that the study cream may be a viable non-prescription, non-corticosteroid therapeutic option for patients affected by mild/moderate inflamed facial SD able to determine significant improvement since the first week.

• Its efficacy on severe forms needs to be better evaluated.

• Digital photography with image processing, that allows for a better evaluation of erythema, is a promising technique for an advanced evaluation of treatment response.