Validation of quality of life and work productivity instruments in patients with chronic hand dermatitis

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INTRODUCTION
- Chronic hand dermatitis (CHD) is an embarrassing and painful inflammatory skin condition which can have a negative impact on quality of life (QoL) and work productivity.
- Valid and reliable (reproducible) measures are needed to evaluate the effectiveness of CHD therapeutic interventions in improving QoL and reducing work impairment.
- The objective of this study was to assess the validity, reproducibility and responsiveness of the Dermatology Life Quality Index (DLQI) and the Work Productivity and Activity Impairment Questionnaire-Chronic Hand Dermatitis (WPAI-ChHD).

METHODS

Stud y design
- This analysis was conducted as part of a multicenter, randomized, double- blind, controlled, parallel-group, 22-day study that assessed the efficacy and safety of pimecrolimus cream 1% in subjects with CHD.
- Subjects were randomized 1:1 to pimecrolimus cream 1% or vehicle (clear).
- The control study was followed by a 23-week open-label study.
- Subjects completed self-administered questionnaires at baseline, day 22 and week 26.
- Subjects' hand condition was assessed at baseline, day 22 and week 26.

Subjects
- A total of 251 men and women aged 18–88 years with mild to moderate CHD present for at least 6 weeks were included in the baseline analyses; 240 subjects were included in the day 22 analyses and 215 subjects were included in the week 26 analyses.

QoL and work productivity measures
- DLQI:
  - Measures six disease-specific domains, i.e., symptoms and feelings, leisure activities, daily activities, work and school, personal relationships, and treatment.
  - Items are rated on a 4-point scale (0 = not at all, 3 = very much).
  - Individual items are summed to generate an overall QoL score, and scores are expressed as percentages, with higher scores indicating greater impairment.
  - Recal period is the last 7 days.

- WPAI-ChHD:
  - Measures work and classroom absenteeism and productivity.
  - Scores are expressed as percentages, with higher scores indicating greater impairment.
  - Recal period is the last 7 days.

Evaluations
- The following properties of the DLQI and WPAI-ChHD were assessed:
  - Validity — ability to differentiate between patients with greater and lesser condition severity.
  - Reproducibility — reliability when there was no change in condition severity.
  - Responsiveness — change in condition severity over time.

RESULTS

Baseline demographics
- Table 1 shows the demographic characteristics, disease severity, QoL, and work productivity of the included subjects in the testing.
- The number of students participating in the study (n = 28) was too small to evaluate classroom absenteeism and productivity.

Table 1. Baseline demographics, disease severity, QoL, and work productivity impairment.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>Post-Drug</th>
<th>Post-Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>44.9±13.3</td>
<td>46.6±13.9</td>
<td>47.1±14.0</td>
</tr>
<tr>
<td>Gender (% female)</td>
<td>57</td>
<td>54</td>
<td>55</td>
</tr>
<tr>
<td>Race (% Caucasian)</td>
<td>85</td>
<td>83</td>
<td>84</td>
</tr>
<tr>
<td>Employment (%)</td>
<td>78</td>
<td>78</td>
<td>78</td>
</tr>
<tr>
<td>Subject (%)</td>
<td>11</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Employed (%)</td>
<td>78</td>
<td>79</td>
<td>79</td>
</tr>
<tr>
<td>Education</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Marital Status</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Employment status</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Work impairment</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Personal relationships</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Activity impairment</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total Key Symptoms Score (TSS)</td>
<td>6.27±1.96</td>
<td>3.76±1.72</td>
<td>3.65±1.70</td>
</tr>
<tr>
<td>Total Key Sign Symptom Score (TSS)</td>
<td>5.50±2.15</td>
<td>3.40±1.30</td>
<td>3.33±1.30</td>
</tr>
<tr>
<td>Total Subject's Overall Self-Assessment (SOA)</td>
<td>2.24±0.30</td>
<td>1.75±0.30</td>
<td>1.70±0.10</td>
</tr>
</tbody>
</table>

Discriminative validity
- Low disease severity scores (IGA, TSS and SOSA) were significant predictors of low DLQI scores at baseline, day 22 and week 26 (p < 0.001 to <0.001), with the exception of the DLQI treatment score (p = 0.114 to <0.001).

Responsiveness (Table 2)
- Treatment success at day 22 and week 26 was a significant predictor of improvement in DLQI scores (p = 0.032 to <0.001), for all but the DLQI personal relationships score at day 22 (p = 0.114 to 0.001).

Reproducibility
- For patients with stable disease severity there were no significant changes from baseline to day 22 or from baseline to week 26 in DLQI scores (p = 0.35 to 0.12), work impairment scores (p = 1.00 to 0.12) or activity impairment (p = 0.17).

Table 2. Responsiveness to clinically meaningful change—p-value from analysis of covariance for the effect of treatment measured by IGA, TSS and SOSA on the prediction of change from baseline to day 22 and week 26 in DLQI and WPAI-ChHD scores.

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Day 22</th>
<th>Week 26</th>
</tr>
</thead>
<tbody>
<tr>
<td>IGA</td>
<td>0.001</td>
<td>0.002</td>
</tr>
<tr>
<td>TSS</td>
<td>0.001</td>
<td>0.002</td>
</tr>
<tr>
<td>SOSA</td>
<td>0.001</td>
<td>0.002</td>
</tr>
</tbody>
</table>

CONCLUSIONS
- The discriminative and evaluative validity of DLQI measures and WPAI-ChHD measures of impairment at work, overall work impairment and activity impairment were established, with the exception of work time missed (possibly due to the low rate of absenteeism).
- Similarly, the responsiveness of these measures to clinically meaningful change was established, again with the exception of work time missed (possibly due to the low rate of absenteeism).
- The reproducibility of all impairment measures was established by showing a lack of change in scores in patients with stable disease severity.

REFERENCES

Based on the results of this study we recommend that the DLOI and WPAI-ChHD be included in investigations of CHD since they are valid measures of the impact of the disease on the patient’s quality of life and work productivity.

The WPAI-ChHD will also be useful in estimating the indirect costs of mild to moderate CHD.