Effect of pimecrolimus cream 1% on quality of life and work productivity outcomes of patients with mild to moderate chronic hand dermatitis

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INTRODUCTION

- Skin diseases, particularly of the hands, have been reported to have a negative impact on patient quality of life (QoL), and account for a large percentage of occupational illness and loss of productivity

- Pimecrolimus cream 1% is a selective inflammatory cytokine inhibitor that has been shown to be effective in treating various forms of dermatitis

- The objective of this analysis was to assess the effect of pimecrolimus cream 1% on patient-reported QoL and work productivity in patients with mild to moderate chronic hand dermatitis (ChHD)

METHODS

Study 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 ChHD

- Patients were randomized 1:1 to pimecrolimus cream 1% or vehicle

Subjects

- A total of 294 males and females aged 18–86 years with mild to moderate ChHD were the subjects of the clinical study

- Of these, 257 (87.4%) completed baseline and follow-up questionnaires and are included in the QoL and work productivity analysis

Evaluations

- The Dermatology Life Quality Index (DLQI)[1] and the Work Productivity and Activity Impairment questionnaire-Chronic Hand Dermatitis (WPAI-ChHD)[2] were self-administered at baseline and day 22

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, to 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
- Recall 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
- Recall period is the last 7 days

Statistics

- Linear regression analyses were performed to explain changes in DLQI and WPAI-ChHD measures from baseline to day 22 as predicted by baseline score, treatment group, suspected etiology (irritant, allergic, endogenous, missing) and palmar surface involvement (yes, no)
- A p-value < 0.05 was required for significance using two-sided hypothesis tests

RESULTS

Baseline characteristics

- Baseline demographic characteristics, disease severity, QoL and work productivity measures are presented in Table 1
- The number of students participating in the study (n = 28) was too small to evaluate classroom absenteeism and productivity

DLQI results (Table 2)

- Regression model: Baseline score and treatment group:
  - There were no significant differences between treatment groups in the change from baseline to day 22 in the DLQI total score or component scores, except the leisure activities score, with the pimecrolimus cream 1% treatment group reporting significantly greater reductions in leisure activities impairment (p = 0.03)

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

Baseline variable	Mean ± SD (n = 257)
Age (years)	44.9 ± 13.3
Gender (% female)	57
Race (% Caucasian)	85
Employed (%)	78
Student (%)	11
Investigators' Global Assessment (IGA)	2.72 ± 0.55
Total Key Symptoms Score (TSS)	6.27 ± 1.96
Subject's Overall Self-Assessment (SOSA)	2.25 ± 0.68
DLQI (%)	
Total	25.1 ± 17.4
Symptoms and feelings	54.6 ± 25.6
Daily activities	19.6 ± 22.8
Leisure activities	18.2 ± 23.5
Work and school	26.5 ± 27.8
Personal relationships	10.6 ± 17.3
Treatment	18.8 ± 22.9
WPAI-ChHD (%)	
Work time missed	0.3 ± 3.7 (n = 196)
Work impairment	17.7 ± 22.3 (n = 197)
Activity impairment	24.6 ± 25.3

- Regression model: Baseline score and treatment group and suspected etiology:
  - Treatment group was a significant predictor for the change in the work and school score at day 22 (p = 0.019), with the pimecrolimus cream 1% treatment group reporting greater reductions in impairment

- Regression model: Baseline score and treatment group and palmar surface involvement:
  - Treatment group was a significant predictor for the change at day 22 in the DLQI total score (p = 0.049), symptoms and feeling score (p = 0.033) and the work and school score (p = 0.014), with the pimecrolimus cream 1% treatment group reporting greater reductions in impairment

Table 2. Regression summary for the effect of treatment group on the prediction of change in DLQI and WPAI-ChHD from baseline to day 22 for suspected etiology and palmar surface involvement subgroups

	Suspected etiology subgroups*	Palmar surface involvement subgroups**
	p value	
DLQI		
Total score	0.079	0.049‡
Symptoms and feelings	0.067	0.033‡
Daily activities	0.636	0.620
Leisure	0.111	0.067
Work and school	0.019‡	0.014‡
Personal relationships	0.239	0.141
Treatment	0.892	0.795
WPAI-ChHD		
Work time missed	0.214	0.330
Work impairment	0.009‡	0.008‡
Activity impairment	0.101	0.109

* Model included terms for baseline score, treatment group, and etiology categories (irritant, allergic, endogenous, missing)
** Model included terms for baseline score, treatment group, and palmar surface involvement (yes, no)
‡ p-value significant at α = 0.05 level

WPAI-ChHD results (Table 2)

- Regression model: Baseline score and treatment group:
  - There were no significant differences between treatment groups in the change from baseline to day 22 for work impairment measures
- Regression model: Baseline score and treatment group and suspected etiology:
  - Treatment group was a significant predictor for the change at day 22 in work impairment due to ChHD (p = 0.009) with the pimecrolimus cream 1% treatment group reporting greater reductions in impairment
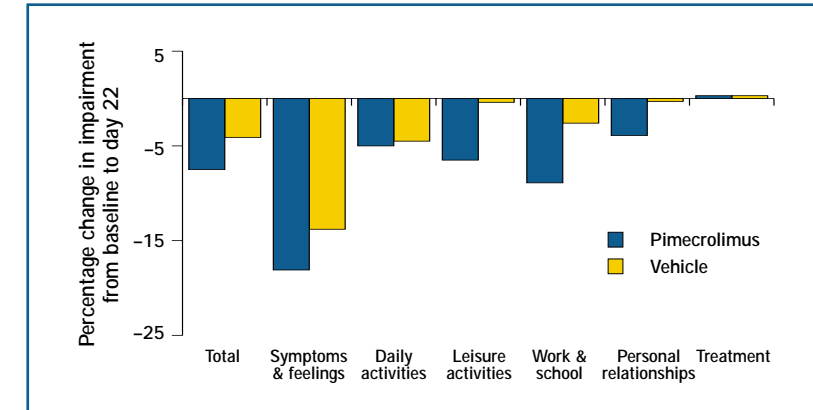- Regression model: Baseline score and treatment group and palmar surface involvement:
  - Treatment group was a significant predictor for the change at day 22 in work impairment due to ChHD (p = 0.008) with the pimecrolimus cream 1% treatment group reporting greater reductions in impairment

Figure 1. Percentage change in DLQI total and component scores from baseline to day 22 by treatment group

CONCLUSIONS

- This study has shown that treatment with pimecrolimus cream 1% has a beneficial effect on the QoL and work productivity of ChHD patients with mild to moderate disease:
  - When suspected etiology and surface involvement were considered, significantly greater improvement in patient-reported outcomes was demonstrated in the pimecrolimus treatment group in comparison with the vehicle treatment group

- Small sample sizes in the subgroup analyses may have adversely affected the power of the study to detect differences for all QoL domains

- Additional research is warranted to confirm which etiology and surface involvement subgroups will benefit most from treatment with pimecrolimus cream 1% in terms of improving QoL and work productivity

REFERENCES

1. Finlay AY, Khan GK. Clin Exp Dermatol 1994;19:210–16
2. Reilly MC, Zbrozek AS, Dukes EM. Pharmacoeconomics 1993;4(5):353–65