

TREATMENT OF SCALP PSORIASIS WITH SHORT-CONTACT CLOBETASOL PROPIONATE SHAMPOO RESULTS IN HIGH PATIENT SATISFACTION AND QUALITY OF LIFE IMPROVEMENT

J. Tan¹, R. Thomas², B. Wang³, D. Gratton⁴, R. Vender⁵, N. Kerrouche⁶, H. Villemagne⁶

¹WINDSOR CLINICAL RESEARCH INC, WINDSOR, ONTARIO, CANADA - ²DERM RESEARCH@888 INC, VANCOUVER, BRITISH COLUMBIA, CANADA - ³SIENA MEDICAL RESEARCH, MONTREAL, QUEBEC, CANADA - ⁴INTERNATIONAL DERMATOLOGY RESEARCH, MONTREAL, QUEBEC, CANADA - ⁵DERMATRIALS RESEARCH, HAMILTON, ONTARIO, CANADA - ⁶MEDICAL AND MARKETING, GALDERMA R&D, SOPHIA ANTIPOLIS, FRANCE

INTRODUCTION

Scalp psoriasis has a significant impact on patients' quality of life (QoL).¹ Most patients are dissatisfied with existing treatments, contributing to sub-optimal adherence.² Clobetasol propionate shampoo integrates a super potent corticosteroid (clobetasol propionate 0.05%) into a once-daily, short-contact shampoo formulation, thus suitable for application on hair-bearing regions such as the scalp. It has been demonstrated to be both efficacious and safe for treatment of moderate to severe scalp psoriasis.^{3,4} In the present study, we evaluate the impact of clobetasol propionate shampoo treatment on patients' skin-related QoL and assess the level of patient satisfaction with this product.

METHODS

Study design

- Single arm, open study in 12 centres in Canada
- Open-label preliminary phase of a randomized, controlled, double-blind study on the maintenance effect of clobetasol propionate shampoo
- Study visit: Baseline, Week 2 and 4

Patient selection

- Male or female patients of 18 years or older
- Patients with "moderate" or "severe" scalp psoriasis based on Global Severity Score (GSS)

Treatment

- All patients received clobetasol propionate shampoo for daily treatment for up to four weeks.

- Patients applied the shampoo once daily in a thin film to dry affected scalp and left it in place for 15 minutes before lathering and rinsing.

Assessments

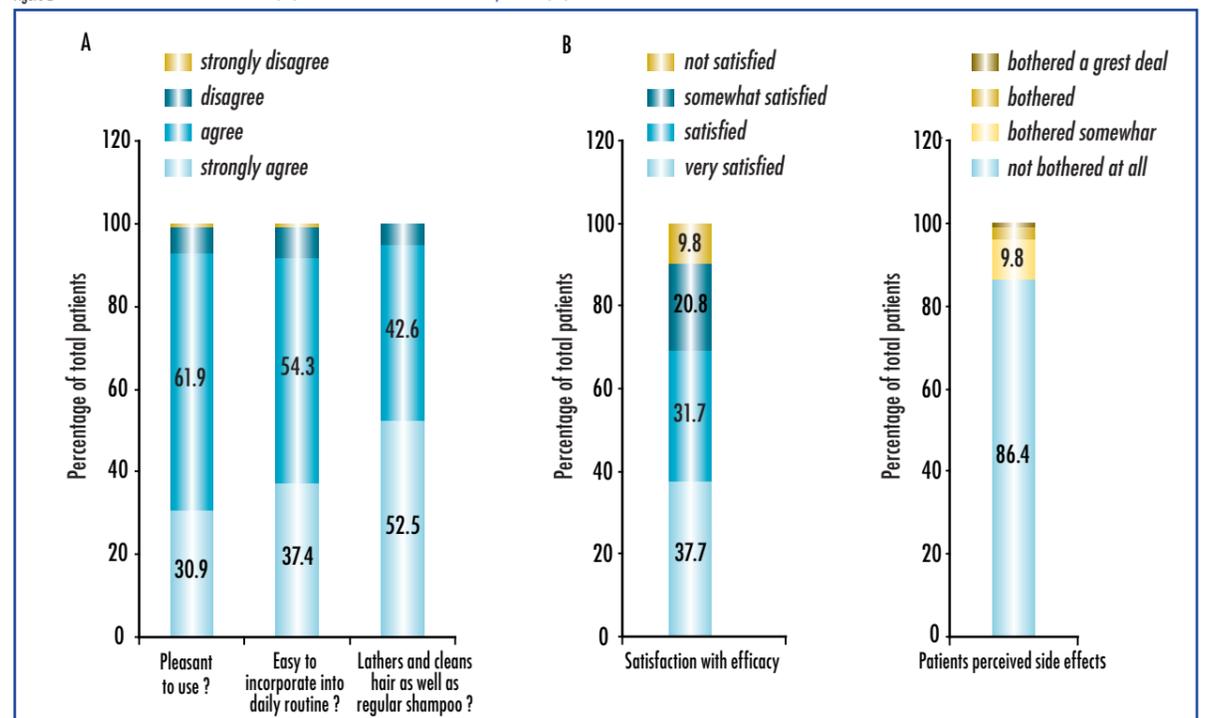
- Dermatology Life Quality Index (DLQI) questionnaire was completed by patients at Baseline and at Week 4.
- A satisfaction questionnaire was completed by patients at Week 4.
- Efficacy was evaluated based on the GSS assessed by investigators at each study visit.
- Safety was monitored based on the adverse events (AEs) reported by the patients and the investigators at each study visit.

RESULTS

STUDY DISPOSITION, DEMOGRAPHY AND DISEASE CHARACTERISTICS AT BASELINE

	Frequency
Enrolled patients	288 (100%)
Completed patients	271 (94.1%)
Discontinued patients	17 (5.9%)
- Adverse event	1 (0.3%)
- Patient request	14 (4.9%)
- Lost to follow-up	1 (0.3%)
- Other	1 (0.3%)
Median age (year)	52
Women	57.6%
Caucasian	92.0%
Moderate scalp psoriasis	58.3%
Severe scalp psoriasis	41.7%
DLQI score (mean ±SD)	7.0±4.9
History of previous scalp psoriasis treatments	90.5%
- Tar shampoo	68.3%
- Steroids	42.3%
- Salicylic acid	25.3%
Unsatisfied by these previous treatments	54.6%

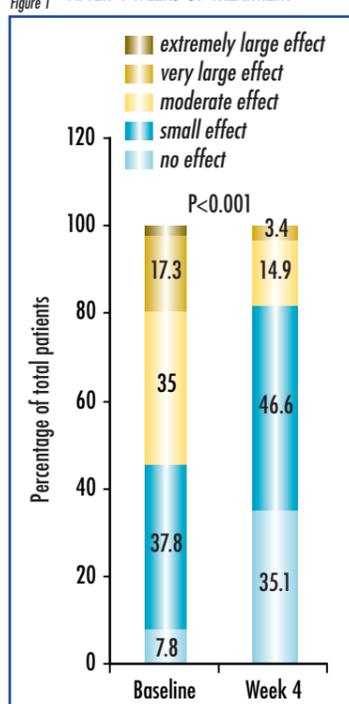
PATIENTS' EVALUATION ON (A) COSMETIC ACCEPTABILITY, AND (B) EFFICACY AND SAFETY OF CLOBETASOL PROPIONATE SHAMPOO TREATMENT



- Very few patients (6%) discontinued before the study completion.
- Most of the patients (90%) had previously used treatments for scalp psoriasis, majority of which (55%) were not satisfied with prior treatments.

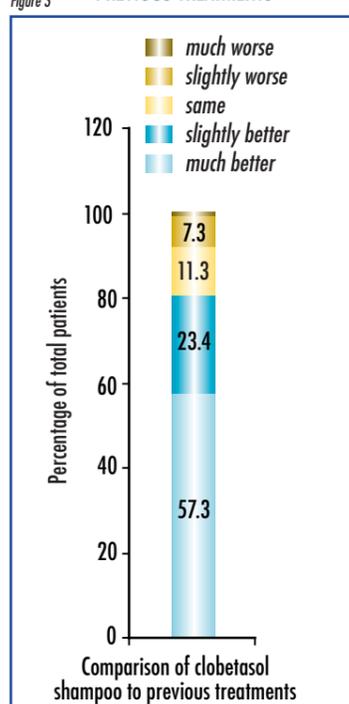
- 92% of patients were satisfied with the overall treatment of clobetasol propionate shampoo. Only 8% were not satisfied by the treatment, significantly less than the number of patients unsatisfied by prior treatments (55%).
- 97% of patients felt better about themselves since the beginning of the treatment, with 57% indicating "much better".

IMPACT ON PATIENTS' SKIN-RELATED QOL (BASED ON DLQI) AT BASELINE AND AFTER 4 WEEKS OF TREATMENT



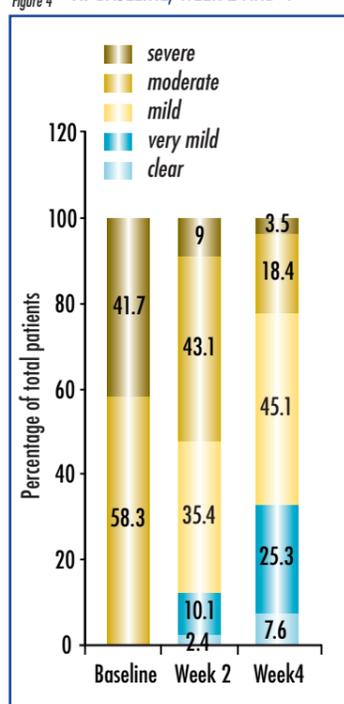
The skin-related QoL of patients was significantly improved (based on Non parametric Wilcoxon Signed test) after 4 weeks daily treatment of clobetasol propionate shampoo.

PATIENTS' PREFERENCE BETWEEN CLOBETASOL PROPIONATE SHAMPOO AND PREVIOUS TREATMENTS



81% of patients preferred clobetasol propionate shampoo to previous treatments and 86% of patients reported that they would use it again.

DISTRIBUTION OF SCALP SEVERITY (BASED ON GSS) AT BASELINE, WEEK 2 AND 4



The clobetasol propionate shampoo treatment was efficacious, as demonstrated by the progressive decrease of GSS.

EFFECT OF TREATMENT WITH CLOBETASOL PROPIONATE SHAMPOO



Safety results

- Only 6 out of 288 patients (2%) reported 7 treatment-related AEs (hair color changes, skin burning sensation and skin discomfort).
- All the treatment-related AEs were of dermatological nature, and mild or moderate in severity.

REFERENCES

1. Choi J, Koo JY. Quality of life issues in psoriasis. *J Am Acad Dermatol* 2003;49 (Suppl.): S57-S61
2. Van de Kerkhof, de Hoop D, de Korte J et al. Patient compliance and disease management in the treatment of psoriasis in the Netherlands. *Dermatology* 2000;20:292-298
3. Jarratt M, Breneman D, Gottlieb AB et al. Clobetasol propionate shampoo 0.05%: a new option to treat patients with moderate to severe scalp psoriasis. *J Drugs Dermatol* 2004;3:367-373
4. Andres P, Poncet M, Sidou F, Sato P. Short-term safety assessment of clobetasol propionate 0.05% shampoo: hypothalamic-pituitary-adrenal axis suppression, atrophagenicity and ocular safety in subjects with scalp psoriasis. *J Drugs Dermatol* 2006;5:328-332

CONCLUSIONS

Daily treatment of short-contact clobetasol propionate shampoo for up to 4 weeks significantly improved skin-related QoL of patients with scalp psoriasis. A large majority were satisfied by the cosmetic acceptability, effectiveness and safety of clobetasol propionate shampoo, and reported that they would use it again.