

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

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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

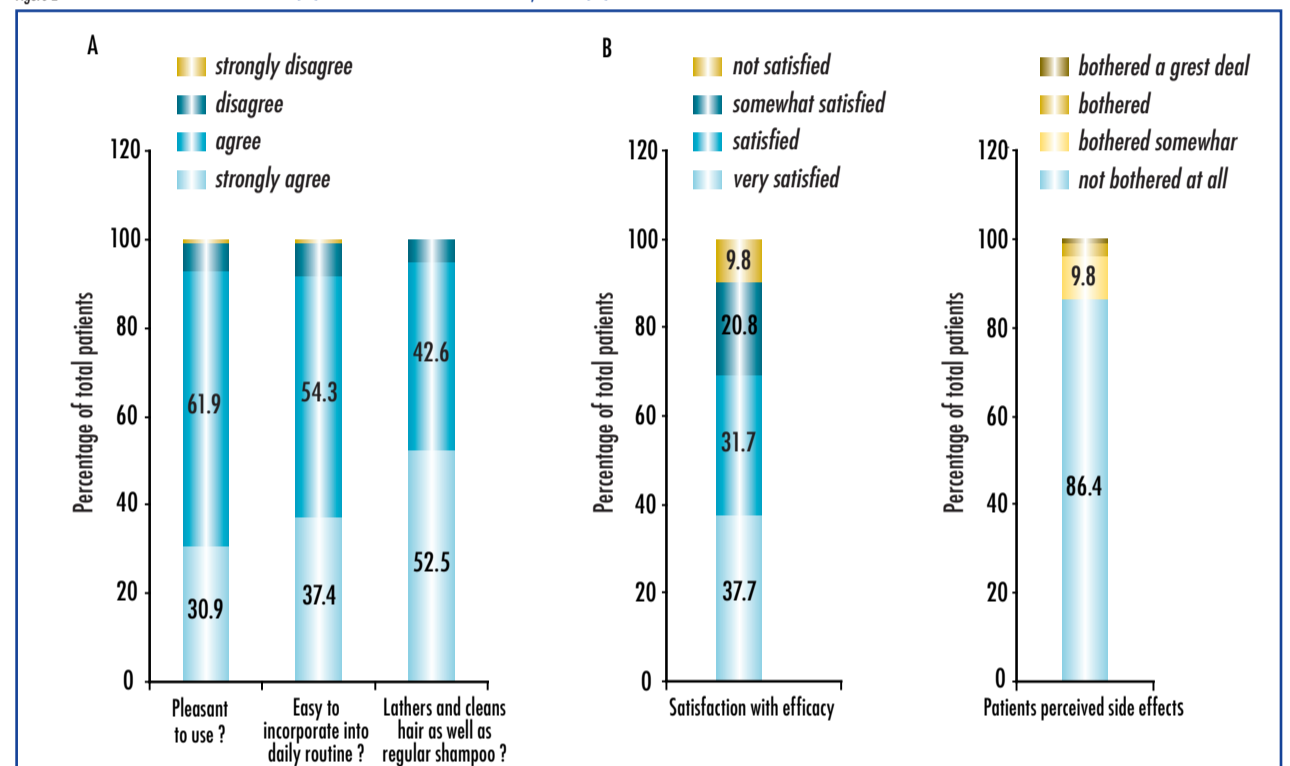
STUDY DISPOSITION,

Table 1 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%

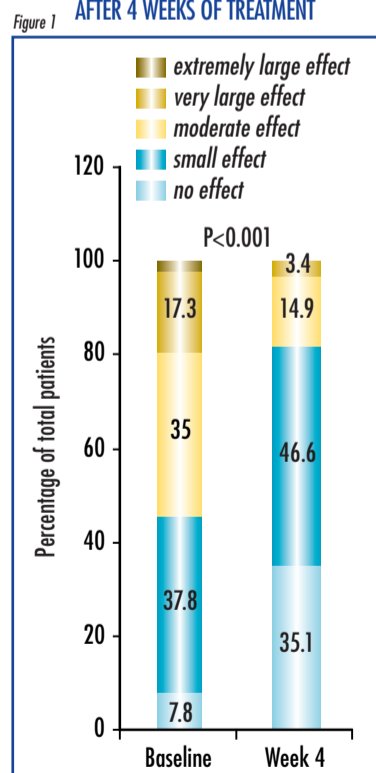
- Very few patients (6%) discontinued before the study completion.
- Most of the patients (90%) had previously used treatments for scalp psoriasis, majority of which (55%) were not satisfied with prior treatments.

Figure 2 PATIENTS' EVALUATION ON (A) COSMETIC ACCEPTABILITY, AND (B) EFFICACY AND SAFETY OF CLOBETASOL PROPIONATE SHAMPOO TREATMENT



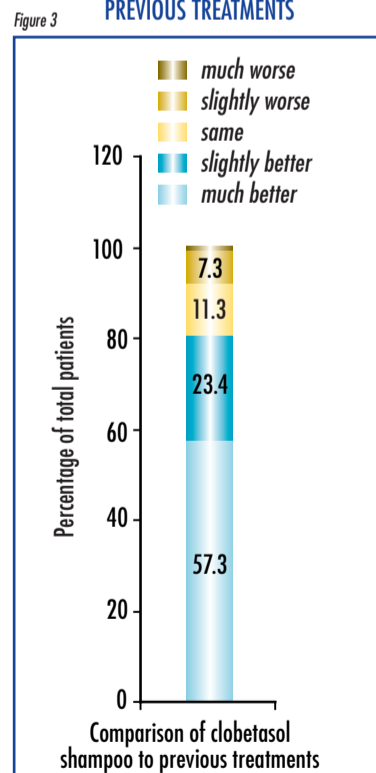
- 92% of patients were satisfied with the overall treatment of clobetasol propionate shampoo. Only 8% were not satisfied by the treatment, significantly less than the number of patients unsatisfied by prior treatments (55%).
- 97% of patients felt better about themselves since the beginning of the treatment,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

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



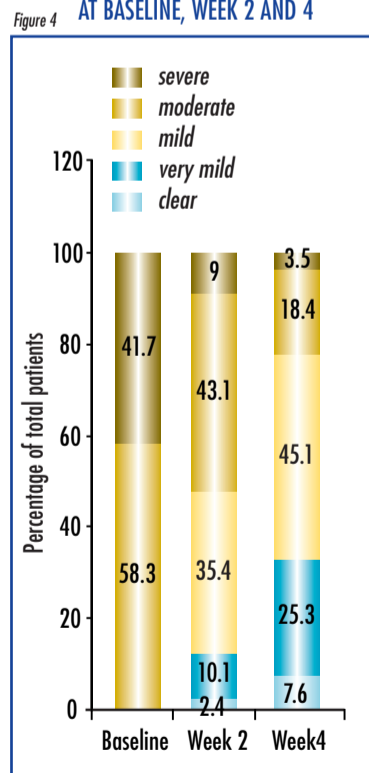
The skin-related QoL of patients was significantly improved (based on Non parametric Wilcoxon Signed test) after 4 weeks daily treatment of clobetasol propionate shampoo.

PATIENTS' PREFERENCE BETWEEN CLOBETASOL PROPIONATE SHAMPOO AND PREVIOUS TREATMENTS



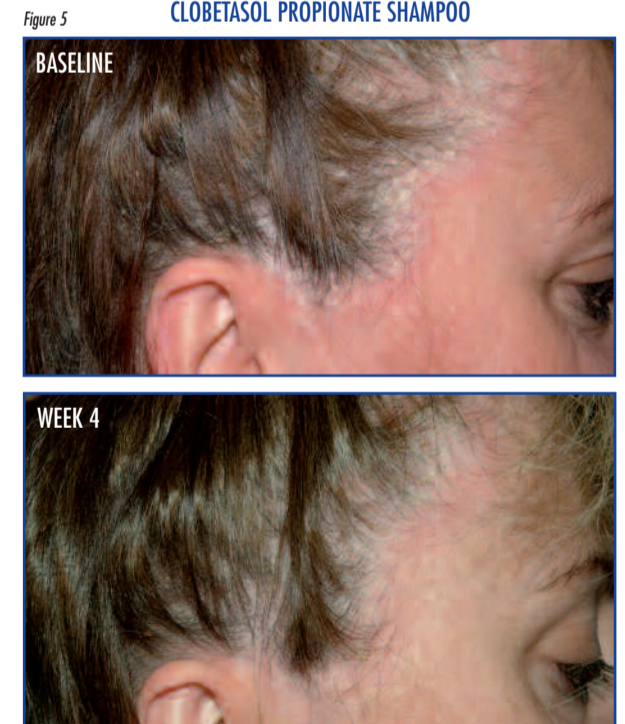
81% of patients preferred clobetasol propionate shampoo to previous treatments and 86% of patients reported that they would use it again.

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.

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4. Andres P, Poncet M, Sidou F, Sato P. Short-term safety assessment of clobetasol propionate 0.05% shampoo: hypothalamic-pituitary-adrenal axis suppression, atrophogenicity 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.