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ORIGINAL ARTICLE

Clobetasol propionate shampoo 0.05% is efficacious and safe for long-term control of moderate scalp psoriasis

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ON BEHALF OF THE CALEPSO STUDY TEAM

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Abstract

We evaluated in this study the efficacy and safety of an alternate regimen using clobetasol propionate 0.05% shampoo (CP shampoo) for long-term control of scalp psoriasis. Patients with moderate scalp psoriasis (Global Severity Score [GSS] of 3 on a 0–5 scale) first received CP shampoo once daily for 4 weeks. Patients with a GSS ≤ 2 were then randomized into the maintenance phase, receiving CP shampoo or vehicle twice weekly. When relapse (GSS > 2) occurred, patients received the 4-week daily CP shampoo treatment. Patients who had a GSS ≤ 2 afterwards reinitiated the twice-weekly maintenance according to the original randomization scheme. Among the 168 patients enrolled, 141 (83.9%) had a GSS ≤ 2 after the initial phase. The median time to first relapse was 141 days with CP shampoo, almost 4 months later than with vehicle (30.5 days; $p < 0.0001$). After 6 months, the percentage of patients who had no relapse was significantly higher with CP shampoo (40.3%) than with vehicle (11.6%; $p < 0.001$). CP shampoo was also safe during the 7-month study period, without leading to more cases of skin atrophy, telangiectasia, hypothalamic-pituitary-adrenal (HPA) axis suppression or adverse events compared to vehicle. The alternate treatment regimen with CP shampoo is efficacious and safe for long-term management of moderate scalp psoriasis.

Key words: *clobetasol propionate, long-term control, maintenance, scalp psoriasis, shampoo, short-contact therapy*

Introduction

Scalp psoriasis is a chronically reoccurring inflammatory disease (1,2). Complete clearance is not a realistic treatment expectation, and the patients' skin-related quality of life is adversely affected by the disease (3–5). Topical agents are the mainstay of treatments, with clinically proven efficacy (6–8). However, many of them are time-consuming to apply, not easily accessible to the scalp, or potentially irritating when used close to the facial area (9). In addition, topical corticosteroids may cause side effects such as skin atrophy, telangiectasia and hypothalamic-pituitary-adrenal (HPA) axis suppression (10,11). These undesirable features of the existing treatments contribute to the generally poor adherence and the low level of satisfaction among patients, further reducing overall efficacy (12–15).

A clobetasol propionate shampoo 0.05% (CP shampoo) was developed recently and the once-daily application is indicated for treatment of moderate scalp psoriasis in Europe. CP shampoo was designed to deliver a super potent corticosteroid in a short-contact formulation in order to minimize the risk of side effects without compromising efficacy. The shampoo vehicle is less messy and less time-consuming to apply than other formulations,

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and is therefore more suitable for scalp treatment (16). Previous study results demonstrated that the 4-week once-daily CP shampoo treatment is efficacious and safe for moderate to severe scalp psoriasis (17–20). Moreover, the treatment significantly improved patients' skin-related quality of life and led to a high level of satisfaction (21).

Owing to the incurable nature of scalp psoriasis, it is important to develop a complete treatment strategy for managing the entire disease cycle. Such a strategy should include an initial phase to allow fast clearance of disease symptoms, followed by a safe long-term maintenance phase during remission and an intensive treatment phase if relapse occurs (9). The ideal medication for such a strategy should be convenient to use, provide a fast onset of action and prevent occurrence of relapse (22). In order to improve long-term efficacy and to reduce cumulative side effects, a few strategies for psoriasis treatment have been developed by combining agents with different modes of action, rotating their usages or using them sequentially (23–25). Pulse therapy, also known as 'weekend therapy', was developed for the long-term management of psoriasis. It includes a 'clearing phase' with daily application of a corticosteroid, and a 'transitional phase' with the medication applied only at weekends (26–28). However, it should be noted that these treatment strategies have not been validated for scalp psoriasis treatment in large clinical studies. Moreover, a strategy on how to treat the disease when relapse occurs has not been developed.

In the present study, we propose an alternate treatment regimen for scalp psoriasis, in which CP shampoo is applied once-daily during initial treatment and relapses, and twice-weekly during remission for long-term maintenance. Based on the established high efficacy and good safety profile of CP shampoo, we hypothesized that it can be used in such a regimen for the complete management cycle of moderate scalp psoriasis.

Materials and methods

This study was conducted in accordance with the Declaration of Helsinki, Good Clinical Practices and local regulatory requirements. The study was reviewed and approved by institutional review boards. All patients provided their written informed consent prior to entering the study.

Patient selection and treatment

A total of 168 patients with moderate scalp psoriasis (Global Severity Score [GSS] of 3 on a 0–5 scale) were enrolled at 12 centres throughout Canada. Female patients were excluded if they were pregnant, nursing or planning a pregnancy. Specified washout periods were required for patients taking systemic treatments or using certain topical treatments on the scalp. CP shampoo (Clobex®/Etrivex®; Galderma SA, Lausanne, Switzerland) or vehicle was applied onto a dry scalp in a thin film and left in place for 15 minutes before lathering and rinsing. During the study, all topical treatments, except super-potent corticosteroids, were authorized for treatment of body psoriasis.

Study design and assessments

This study consisted of an open label initial treatment phase, and a randomized, double-blind, vehicle-controlled maintenance phase. Enrolled patients first entered the initial phase, where they applied CP shampoo once daily on the affected scalp area for up to 4 weeks. Patients with a GSS ≤ 2 (clear, very mild or mild) were randomized into the maintenance phase to apply CP shampoo or its vehicle twice weekly (3 days apart) on the entire scalp for up to 6 months.

During the maintenance phase, patients were evaluated every 4 weeks for relapse, defined as a GSS > 2 (moderate, severe or very severe scalp psoriasis). When relapse occurred, patients were requested to apply CP shampoo once-daily for 4 weeks. If the disease control was not regained (GSS > 2) after the 4-week daily CP shampoo treatment, patients exited the study. If the disease control was regained (GSS ≤ 2), the twice-weekly maintenance regimen was then re-instituted in accordance with the original randomization scheme. Further relapses were treated in the same manner. This treatment schedule is hereafter referred to as the alternate treatment regimen (Figure 1).

At each study visit, besides GSS, the investigator assessed the extent of the disease on a 6-point scale and individual sign scores (including scaling, erythema and plaque thickening) on a 5-point scale. The patients were requested to assess their pruritus intensity on a 4-point scale. Safety assessments at each study visit included the burning sensation, skin atrophy, telangiectasia and adverse events (AE). HPA axis activity was examined at the end of the study, using an assay of the morning serum cortisol level with a pre-established 5 μg/dl threshold (20).

A patient satisfaction questionnaire was completed at the end of the study.

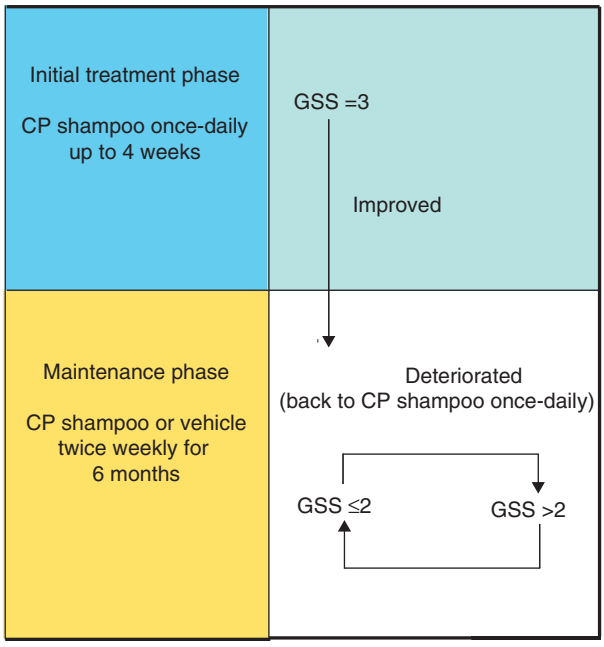

Figure 1. Study design (Global Severity Score [GSS] full scale: 0 = clear, 1 = very mild, 2 = mild, 3 = moderate, 4 = severe, 5 = very severe).

Statistical methods

The maintenance effect of CP shampoo was assessed by comparing the time to the first relapse in the shampoo group with that in the vehicle group using the Kaplan-Mayer survival test (PROC LIFETEST from SAS). The Cochran-Mantel-Haenszel (CMH) test stratified by centre was utilized to analyze the percentage of patients who had no relapse at each study visit and the total number of relapses over the maintenance phase. To avoid bias caused by missing values, patients who discontinued before having the first relapse were considered as having a relapse at the subsequent visit (ITT worst-case population). The individual sign scores and pruritus score at the time of the first relapse were descriptively analyzed.

The worst scores of burning, skin atrophy and telangiectasia during the entire study, as well as the scores of skin atrophy, telangiectasia and HPA axis at the last study visit were analyzed using the CMH statistic test stratified by centre, on safety population.

Every test was two-sided, at the 0.05 significance level.

Results

Among the 168 patients who entered the initial phase with moderate scalp psoriasis, 141 (83.9%) of them had clear, very mild or mild disease (GSS ≤ 2) after 4 weeks of daily CP shampoo treatment. More than 85% of patients experienced none or only mild erythema, scaling, plaque thickening and pruritus after the initial phase treatment.

A total of 136 patients (81%) with a GSS ≤ 2 were subsequently randomized into the maintenance phase to receive CP shampoo or vehicle twice weekly (Figure 2). At the baseline of the maintenance phase, the majority of patients were Caucasians, with a mean age of 50 years. The global and individual severity scores were comparable between the two groups at baseline (Table I). Fewer patients in the shampoo group discontinued (9 patients, 13.4%) compared with the vehicle group (17 patients, 24.6%). The most frequent reason for discontinuation was 'patient's request', with 7.5% and 23.2% from the CP shampoo group and the vehicle group, respectively.

Efficacy results

At all study visits, the percentage of patients who had no relapse was significantly greater with CP shampoo than with vehicle (at least $p < 0.01$) (Figure 3). At month 1, only about 44% of patients in the vehicle group had no relapse; whereas this rate was observed about 4 months later in the CP shampoo group. After 6 months of maintenance treatment, the percentage of patients who had no relapse was 40.3% with CP shampoo, compared with 11.6% with vehicle. The median times to the first relapse, defined as the time when 50% of patients had their first relapse, were calculated to be 30.5 days with vehicle and 141 days with CP shampoo ($p < 0.0001$).

Among the patients who had relapse and entered the alternate treatment regimen, a significantly greater percentage of those in the CP shampoo group (73.2%) had experienced only one relapse over 6 months compared with those in the vehicle group (34.1%; $p < 0.001$) (Figure 4). Correspondingly, more patients in the vehicle group had two or three relapses (38.3% and 27.6%, respectively) during the maintenance phase than in the CP shampoo group (16.8% and 10.0%, respectively; $p < 0.001$).

At the time of the first relapse, the GSS was similar between the CP shampoo group and the vehicle group, with more than 90% of patients having moderate psoriasis. However, when comparing the individual severity scores, the disease tended to be slightly less severe with CP shampoo than with vehicle: the percentage of patients who had less than 20% of their scalp affected was 54.3% and 38.6% with CP shampoo and vehicle, respectively. In addition, more patients in the CP shampoo group did not experience pruritus (17.1%) compared with in the vehicle group (3.5%).

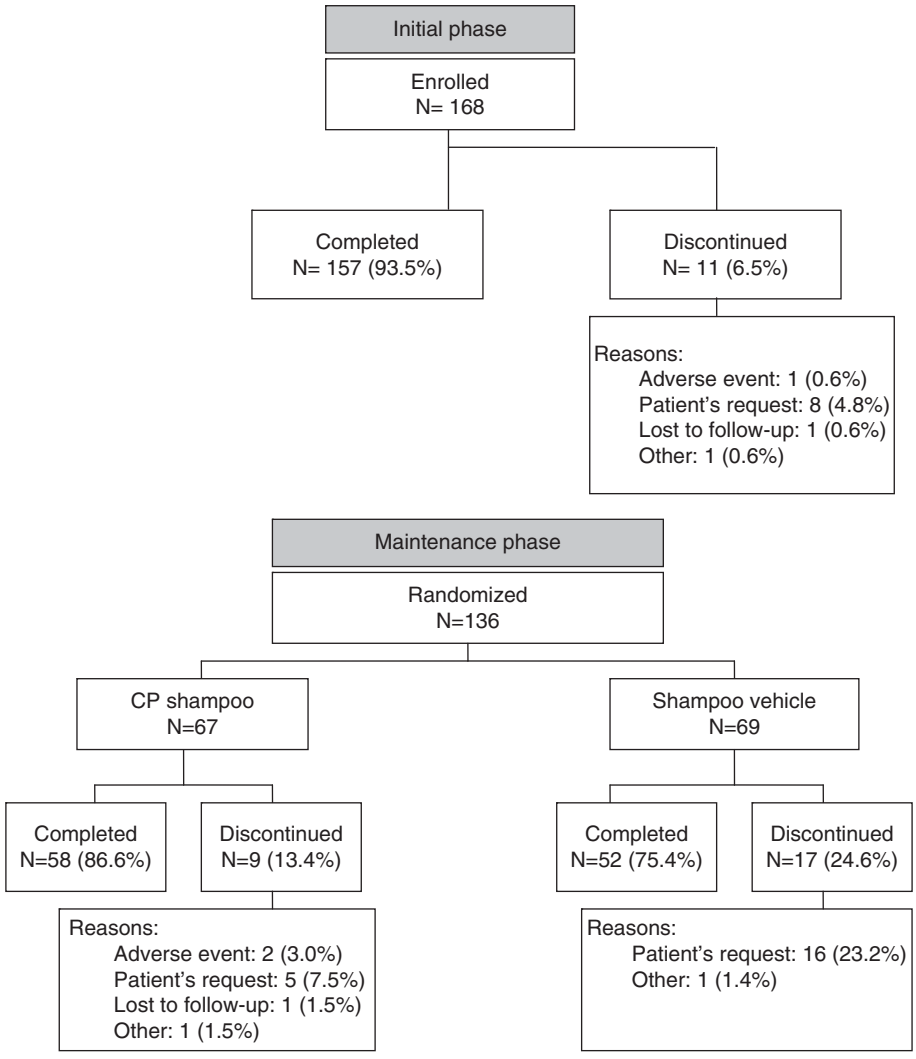

Figure 2. Flow chart of patient disposition (ITT population).

Safety results

During the entire study period (1-month initial phase plus 6-month maintenance phase), CP shampoo was applied for 79.3 days and 59.5 days among patients from the shampoo group and the vehicle group, respectively. After the initial treatment phase, application of CP shampoo in the vehicle group was due to the alternate treatment regimen at times of relapse. Local tolerability mean worst scores during the study were similar between the two groups; more than 80% of patients experienced no sign of burning and more than 97% had no skin atrophy or telangiectasia (Table II). Two patients in the CP shampoo group and one in the vehicle group had mild telangiectasia. However, those signs were either transient or already present at study baseline.

At the end of the study, the morning serum cortisol level was measured and no notable HPA axis suppression was observed. Only one patient in the vehicle group had a slightly lower serum cortisol level (4.9 μg/dl) than the established threshold (5.0 μg/dl), and the condition was deemed to be unnecessary for any follow-up.

A total of 84 adverse events (AEs) were reported by 57 patients during the maintenance phase. More AEs occurred in the vehicle group (50 events) than in the CP shampoo group (34 events). Only eight treatment-related AEs were reported: three with CP shampoo and five with vehicle. One patient in the CP shampoo group experienced asthma, which was reported to be a severe treatment-related adverse event, and was resolved by the end of the study.

Patient satisfaction

A satisfaction questionnaire comprising nine items was completed by patients at the end of the study,

Table I. Demographics and disease characteristics at baseline of the maintenance phase (ITT population).

		CP shampoo (n = 67)	Vehicle (n = 69)	Total (n = 136)
Sex, n (%)	Male	35 (52.2)	33 (47.8)	68 (50.0)
	Female	32 (47.8)	36 (52.2)	68 (50.0)
Age, years	Mean ± SD	50.2 ± 15.5	49.8 ± 17.1	50 ± 16.2
	Min, Max	20, 79	18, 78	18, 79
Race, n (%)	Caucasian	62 (92.5)	62 (89.9)	124 (91.2)
	Asian	3 (4.5)	6 (8.7)	9 (6.6)
	Hispanic	1 (1.5)	1 (1.4)	2 (1.5)
	Other	1 (1.5)	–	1 (0.7)
Global Severity Score, n (%)	0: Clear	11 (16.4)	10 (14.5)	21 (15.4)
	1: Very mild	33 (49.3)	32 (46.4)	65 (47.8)
	2: Mild	23 (34.3)	27 (39.1)	50 (36.8)
Erythema, n (%)	0–1: None – Mild	57 (85.1)	59 (85.5)	116 (85.3)
	2–3: Moderate – Severe	10 (14.9)	10 (14.5)	20 (14.7)
Scaling, n (%)	0–1: None – Mild	63 (94.0)	58 (84.1)	121 (88.9)
	2: Moderate	4 (6.0)	11 (15.9)	15 (11.1)
Plaque thickening, n (%)	0–1: None – Mild	66 (98.5)	66 (95.7)	132 (97.1)
	2: Moderate	1 (1.5)	3 (4.3)	4 (2.9)
Extent of disease, n (%)	0–1: None – <20%	58 (86.5)	58 (84.1)	116 (85.3)
	2–5: 20–100%	9 (13.5)	11 (15.9)	20 (14.7)
Pruritus, n (%)	0–1: None – Mild	65 (97.0)	66 (95.7)	131 (96.4)
	2–3: Moderate – Severe	2 (3.0)	3 (4.3)	5 (3.6)

and the responses to three of them are illustrated in Figure 5. There were 100% of patients from the shampoo group and 83.1% from the vehicle group who considered that the alternate treatment regime was easy to incorporate into their daily routine, which was mirrored by the high compliance rate observed in the study (over 95% in both groups). Moreover, 72.7% of patients from the CP shampoo group preferred the twice-weekly treatment for a long period, compared to a daily treatment in case of relapse. There were 86.0% of patients from the CP shampoo group willing to continue the treatment in the same way, and 57.1% reported that they could adopt such a regimen for as long as 1 year.

Regarding the efficacy and safety of the twice-weekly maintenance treatment, significantly more patients from the CP shampoo group than the vehicle group agreed that the treatment was enough to control their disease (73.7% versus 39.7%; $p<.001$), considered themselves not bothered at all by side effects (93% versus 79.7%; $p<0.05$), and were satisfied or very satisfied with the overall treatment (84.2% versus 59.7%; $p<0.01$).

Discussion

The scalp remains one of the most difficult to treat areas in psoriasis patients. In spite or because of that, there were only seven well-designed controlled

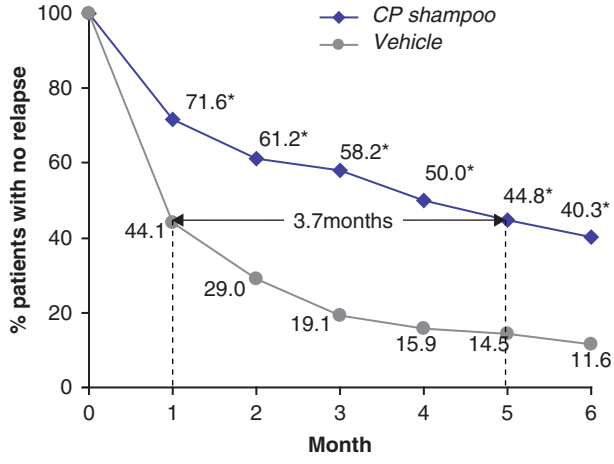

Figure 3. Percentage of patients with no relapse at each study visit (ITT worst-case population). Patients who discontinued before having the first relapse were considered as having a relapse at the following visit. *$p<0.01$.

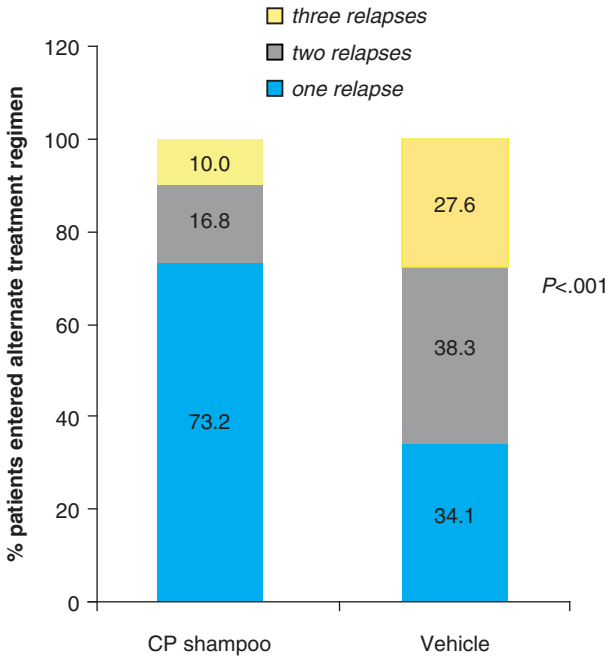

Figure 4. Percentage of patients who had one, two or three relapses during the study (ITT worst-case population).

studies focused specifically on scalp treatments according to a recent meta-analysis on topical therapies of plaque-type psoriasis (22).

In the present study, we propose a novel alternate treatment regimen with CP shampoo for the complete management of moderate scalp psoriasis. The regimen includes a once-daily treatment phase for 4 weeks and a twice-weekly maintenance phase for up to 6 months (Figure 1). Such a treatment regimen allows rapid clearance of symptoms during relapse, and offers a safe preventive treatment when disease is under control. CP shampoo is suitable to be used in the entire management cycle due to its unique profile combining great efficacy, good safety and high patient satisfaction.

Table II. Local tolerability mean worst score during the study (safety population).

		CP shampoo $n = 67$	Vehicle $n = 69$	p-value
Burning, n (%)	0: None	58 (86.6)	56 (81.2)	0.063
	1: Mild	7 (10.4)	9 (13.0)	
	2: Moderate	2 (3.0)	4 (5.8)	
Skin atrophy, n (%)	0: None	66 (98.5)	69 (100.0)	0.527
	1: Mild	1 (1.5)	–	
Telangiectasia, n (%)	0: None	65 (97.0)	68 (98.6)	0.806
	1: Mild	2 (3.0)	1 (1.4)	

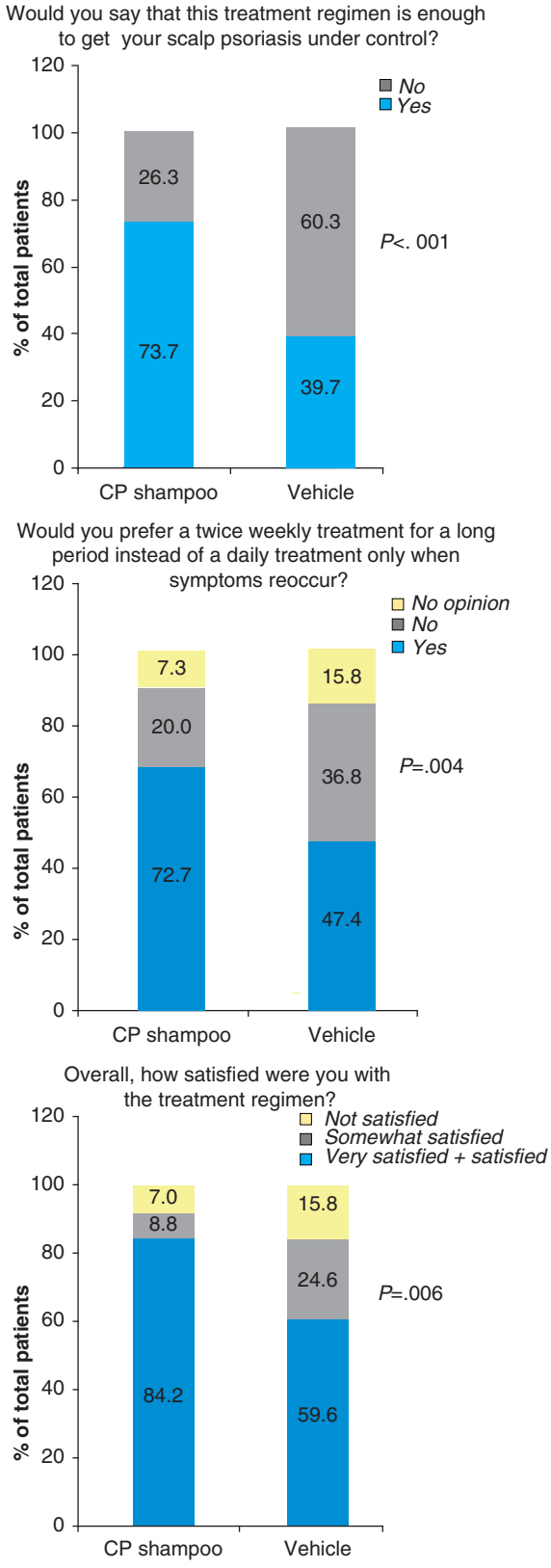

Figure 5. Results of patient satisfaction questionnaires at the end of the study.

The once-daily CP shampoo application has been shown to be efficacious for treatment of moderate to severe scalp psoriasis (17–19). We demonstrate in this study that, when utilized twice-weekly in the alternate treatment regimen, CP shampoo is significantly more efficacious than the corresponding vehicle in preventing relapse. After 1 month, about 50% of patients receiving vehicle already had relapse. Patients receiving CP shampoo did not reach the 50% relapse threshold until about 5 months. After 6 months, 40.3% of patients with CP shampoo were free of relapse compared with 11.6% with vehicle. Among those who had relapsed during the 6-month maintenance phase, significantly more patients from the CP shampoo group had only one relapse, compared to the vehicle group. The results of a patient satisfaction questionnaire on the effectiveness of treatment mirrored the investigator's assessments. Significantly more patients receiving CP shampoo considered the treatment enough to manage their disease and were satisfied or very satisfied with the overall treatment. Therefore, clinicians can adjust the dosage of CP shampoo to utilize the same medication effectively for both intensive treatment and long-term maintenance.

The prolonged usage of topical corticosteroids may pose a safety concern for patients and physicians (10,11,29), and the therapies are typically authorized for only 4 weeks. CP shampoo has a good short-term safety profile, with no case of HPA axis suppression or skin atrophy observed after 4 weeks of daily application (20). In the present study, the long-term safety of CP shampoo was evaluated during the 7-month study period. Patients from the vehicle group reported more AEs and more treatment-related AEs than those from the shampoo group. Very few cases of burning, skin atrophy and telangiectasia were reported and no HPA axis suppression was observed. These assessments by investigator were confirmed by the results of patient satisfaction questionnaire, with significantly more patients from the CP shampoo group than the vehicle group reporting to be not bothered at all by side effects (93.0% versus 79.7%). Taken together, the short-contact shampoo formulation of clobetasol propionate can be utilized for a prolonged period without leading to notable side effects.

Patient-reported outcomes during the initial phase of this study were summarized in a previous report, in which we demonstrated that the once-daily CP shampoo treatment significantly improved the skin-related quality of life and resulted in high patient satisfaction (21). At the end of the initial phase, more than 90% of total patients were satisfied with the cosmetic acceptability of CP shampoo, considering it pleasant to use and noting that it cleans as well as regular shampoos. This high level of satisfaction regarding CP shampoo is consistent with previously reported patient's vehicle preference for scalp psoriasis treatment (16). Regarding the alternate treatment regimen, we demonstrate in this report that more than 80% of patients from both groups considered it easy to be incorporated into their daily routine. This positive feedback should improve patient adherence, since 'time-consuming' was considered as the most troublesome aspect of treatments by 50% of patients in a European survey (15). Significantly more patients receiving CP shampoo preferred the twice-weekly maintenance treatment instead of treating only when relapses occur and were willing to continue the treatment in the same way for up to 1 year. The high degree of patient satisfaction reported in both initial and maintenance phases translated to the particularly good adherence observed during the study. Although the results of clinical studies do not always reflect the reality during outpatient visits, the good compliance observed in this study is nevertheless very encouraging.

In summary, the alternate treatment regimen with CP shampoo is efficacious and safe for the complete management of moderate scalp psoriasis. This treatment also leads to high patient satisfaction, which may increase adherence and result in even greater overall treatment efficacy.

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