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The Evolving Role of Therapeutic Shampoos for Targeting Symptoms of Inflammatory Scalp Disorders

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ABSTRACT

Scalp lesions are common among patients with psoriasis, seborrheic dermatitis and a number of other inflammatory and fungal conditions. Topical corticosteroids are a mainstay of treatment for many scalp dermatoses and they significantly reduce erythema, scaling and pruritus. Conventional corticosteroid formulations such as cream and ointments are often difficult or time consuming for patients to apply and may produce undesirable cosmetic effects. Medicated shampoos provide a more convenient alternative for patients who require topical administration of corticosteroids for scalp conditions. Tar shampoos have long been used to treat psoriasis and are effective for the long-term maintenance of remission in patients who respond to therapy. Antifungal shampoos are effective for the treatment of seborrheic dermatitis and other mycotic conditions. A shampoo formulation containing fluocinolone acetonide, 0.01% is also approved for the treatment of seborrheic dermatitis. One superpotent corticosteroid shampoo (clobetasol propionate 0.05%; Clobex® Shampoo) is approved in the United States (U.S.) for once-daily treatment of psoriasis of the scalp. The results of a 2007 pilot study also demonstrated that clobetasol propionate shampoo improved the signs and symptoms of seborrheic dermatitis. These findings suggest that high-potency corticosteroid shampoos may provide an important option for topical corticosteroid therapy in dermatologic conditions affecting the scalp.

INTRODUCTION

Scalp lesions are a common yet challenging complaint among patients with a broad range of dermatologic conditions, including, but not limited to, psoriasis, seborrheic dermatitis and atopic dermatitis. Inflammation, pruritus, scaling and alopecia are common clinical signs and symptoms that occur across many different scalp dermatoses.[1] Scalp tissue is especially susceptible to mycotic, parasitic and inflammatory disorders due to its relatively high follicular density and the abundance of sebum and desquamated skin.[1] In addition, the use of combs and other grooming implements further exacerbates scalp infection and inflammation by producing friction injury and introducing microorganisms into the skin.[1]

Topical corticosteroids produce anti-inflammatory and antipruritic effects, and are widely used to treat a variety of inflammatory dermatologic conditions. These agents are available in many different strengths, and are often rated in potency from class 1 (superpotent, e.g., clobetasol propionate) to class 7 (least potent, e.g., hydrocortisone).[2] Topical corticosteroids produce significant rapid improvement in erythema, scaling and pruritus in patients with psoriasis and seborrheic dermatitis, and are effective for the treatment of atopic dermatitis.[2–5]

Traditional corticosteroid ointments or creams may be messy; the application of them may be time consuming or difficult for patients to apply. Patients are often dissatisfied with the cosmetic appearance of their hair when topical medications are applied to the scalp, which may include hair discoloration, dryness or unpleasant odors.[6] Medicated shampoos may provide greater convenience than conventional creams or ointments for the treatment of scalp lesions and a number of these products have recently become available to treat inflammatory disorders of the scalp. Shampoos are applied for a specified period of time and are then rinsed from the hair, which may be easier to use than leave-on products that remain on the skin for extended periods of time.[7] Antifungal shampoos are a mainstay in the treatment of conditions with a mycotic component, including seborrheic dermatitis, tinea capitis and others. A low-potency corticosteroid shampoo (fluocinolone acetonide, 0.01% shampoo) has long been available for the treatment of seborrheic dermatitis and, more recently, a superpotent corticosteroid (clobetasol propionate, 0.05%, Clobex®, Galderma Laboratories, Ft. Worth, TX) has become available in a shampoo formulation for the treatment of psoriasis.

This paper provides an overview of the use of medicated corticosteroid shampoos in the treatment of psoriasis, seborrheic dermatitis and other inflammatory scalp dermatoses.

Scalp Lesions Common in Inflammatory Dermatoses

Psoriasis and seborrheic dermatitis are among the most common dermatologic conditions affecting the scalp. These disorders may be difficult to distinguish from one another, and identification is thus often confused.[8] Psoriasis of the scalp affects approximately 50–80% of patients with psoriasis.[9] Scalp lesions

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are associated with considerable pain, discomfort and pruritus, and in rare cases may cause potentially permanent scarring alopecia.[10] Scalp desquamation in patients with psoriasis is associated with significantly diminished quality of life.[11] In addition, scalp psoriasis is often more difficult to treat than psoriasis affecting other parts of the body due to the absorption of topical agents by the hair, the close proximity of sensitive facial skin restricts the choice in corticosteroid potency, and generally poor adherence of patients for treatment involving the scalp.[9] Scalp lesions may also extend beyond the hairline to involve the face or retroauricular folds, where high-potency steroids should not be used or used sparingly.[10,12]

Seborrheic dermatitis is a common, recurrent mycotic disorder of the scalp that is associated with Malassezia species.[1] The clinical signs and symptoms of seborrheic dermatitis include pruritus and the presence of red, scaly lesions affecting the scalp, face, and upper trunk.[13] Although psoriasis and seborrheic dermatitis often resemble one another, psoriasis is more likely to cause well-demarcated erythematous plaques that may also be present on the rest of the body, usually on the knees, elbows and buttocks. In contrast, lesions of seborrheic dermatitis are generally diffuse and are usually limited to the face and scalp—especially the glabella and nasolabial folds; however, it can also be seen on the mid-chest.[8]

Pruritus, erythema and scaling are also common to many other dermatologic conditions that affect the scalp. Atopic dermatitis is a common disorder that causes intense pruritus, as well as oozing, scaling and crusting of the skin, which affects many different sites, especially the antecubital fossae and popliteal fossae. It can also be seen on the scalp.[14] Tinea capitis (ringworm) occurs in inflammatory and noninflammatory forms.[1] Both forms can cause alopecia, and the inflammatory form is also associated with scalp pustules, abscesses and painful purulent lesions (kerions).[1] Pityriasis rubra pilaris is characterized by follicular hyperkeratotic papules and large, scaly erythematous plaques, often beginning on the face and scalp and, in some cases, progressing to exfoliative erythroderma.[15] Pemphigus foliaceous causes superficial pruritic blisters and crusted sores that often appear initially on the face and scalp.[16] Lichen planopilaris (lichen planus lesions affecting the scalp) is a scarring form of alopecia of unknown etiology that is characterized by scaling, atrophy, erythema inflammation and keratotic follicular papules.[17,18] Without treatment, lichen planopilaris may cause the permanent destruction of the follicles, resulting in irreversible alopecia.[18] Several other forms of alopecia also involve inflammatory lesions of the scalp, including cicatricial alopecia and folliculitis decalvans.[19,20]

Medicated Shampoos for Psoriasis

Tar shampoos have long been used to treat scalp psoriasis. These shampoos can produce long-lasting clearing of lesions and are superior to commercial, non-medicated shampoos for the long-term maintenance of improvement after initial therapy for scalp psoriasis.[21,22] An eight-week, multicenter, randomized, open-label clinical trial found that the addition of tar shampoo (Polytar Liquid®, Stiefel Laboratories [UK] Limited, Berkshire, UK) to the topical vitamin D analogue, calcipotriene, did not significantly increase the number of patients with marked improvement or clearance of psoriasis (55.9% of patients with calcipotriene lotion plus tar shampoo versus 51.7% with calcipotriene lotion alone). The addition of tar shampoo was associated with significantly greater reduction in pruritus than calcipotriene alone (P=0.032).[22] In addition to tar shampoos, shampoos containing anthralin, salicylic acid or selenium are also used for the treatment of psoriasis.[3] However, these shampoos have been associated with significant limitations, such as unpleasant odor or staining of hair (e.g., with coal tar or anthralin shampoos) or a lack of well-controlled clinical trial data regarding their efficacy for the treatment of psoriasis (e.g., with shampoos containing salicylic acid or selenium).[3]

As a class, topical corticosteroids are the most commonly used treatments for psoriasis by both primary care physicians and dermatologists.[23] Corticosteroid solutions (e.g., clobetasol propionate 0.05% solution) have been used since the 1970s to treat psoriasis and other inflammatory scalp dermatoses.[24] Twice-daily application of clobetasol propionate 0.05% solution for moderate-to-severe scalp psoriasis has been shown to significantly improve psoriasis signs and symptoms, including erythema, induration, scale and pruritus. After two weeks, approximately 80% of patients treated with clobetasol propionate 0.05% solution exhibited an improvement in psoriasis severity of at least 50% from baseline, compared with approximately 20% of patients treated with placebo solution (P=0.0001).[24] Only one superpotent corticosteroid shampoo is available in the United States (U.S.). Clobetasol propionate 0.05% shampoo (Clobex Shampoo) is a once-daily, short-contact, shampoo treatment for moderate-to-severe scalp psoriasis.[25] As described in detail below, several randomized, controlled clinical trials have demonstrated that once-daily application of clobetasol propionate 0.05% shampoo for four weeks is a safe, well-tolerated and effective option for the treatment of moderate-to-severe scalp psoriasis in adults.

Andres and colleagues conducted a randomized, parallel-group, investigator-blinded clinical trial to compare the cutaneous safety of clobetasol propionate shampoo with a clobetasol propionate 0.05% gel formulation (Dermoval™/Temovate®, GlaxoSmithKline, Pittsburgh, PA) when applied to the scalp, as well as the potential for corticosteroid-induced ocular injury (e.g., increased intraocular pressure) that might occur during rinsing.[26] A total of 26 patients with scalp psoriasis were randomized to clobetasol propionate shampoo or clobetasol propionate gel for up to four weeks; the mean age was 38 years (SD, nine years) in the shampoo group and 30 years (SD, 10 years) in the gel group.

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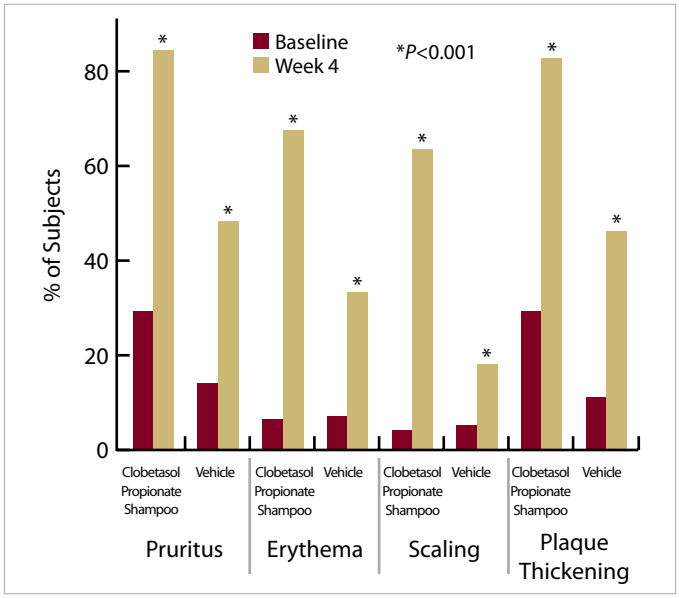
Clobetasol propionate shampoo produced significantly less skin thinning than clobetasol propionate gel.[26] No ocular adverse events (e.g., stinging, burning, changes in intraocular pressure) were noted for either treatment group.[26] The gel formulation resulted in suppression of hypothalamic-pituitary axis (HPA) function in 16% of patients after the first week of treatment, whereas none of the patients in the clobetasol propionate shampoo group exhibited HPA suppression.[26] The investigators suggested that the short-contact shampoo formulation may be associated with less risk of corticosteroid-related adverse events than conventional topical agents that remain in contact with the skin for longer periods of time.[26] In another study, twice-weekly application of clobetasol propionate shampoo for 2.5, 5 or 10 minutes twice-weekly on wet scalp for up to four weeks did not suppress HPA function or induce skin atrophy in adult patients with seborrheic dermatitis.[27]

The efficacy and safety of clobetasol propionate 0.05% shampoo were evaluated in a randomized, double-blind, vehicle-controlled clinical trial of 142 patients with moderate-to-severe scalp psoriasis.[3] Patients applied clobetasol propionate shampoo or vehicle shampoo once daily for 15 minutes for four weeks. Treatment success (defined as a global psoriasis rating of "clear" or "minimal") was obtained for 42% of patients who used clobetasol propionate shampoo versus 2% of patients who used vehicle shampoo (P<0.001).[3] The success rate with clobetasol propionate shampoo remained higher than with the vehicle shampoo two weeks after treatment was discontinued. A physician global severity rating of "mild" psoriasis or better was noted for 72% of patients with clobetasol propionate shampoo versus 15% with vehicle shampoo (P<0.001).[3] Clobetasol propionate shampoo was also significantly more effective than vehicle shampoo for individual symptoms of pruritus, erythema, scaling, and plaque thickness (Figure 1).[3] Drug-related adverse events (e.g., stinging or burning) were more common with the vehicle shampoo (21% of patients) than with clobetasol propionate shampoo (14%). No skin atrophy, telangiectasia, acne or severe adverse events were noted for either treatment group.[3]

Subsequent studies have compared clobetasol propionate shampoo with other topical psoriasis medications. Reygagne and colleagues conducted a randomized, investigator-blinded clinical trial in which 151 patients with moderate-to-severe scalp psoriasis were assigned to receive four weeks of treatment with either 0.05% clobetasol propionate shampoo once daily or 0.005% calcipotriene solution (Dovonex®/Daivonex™, Leo Pharma, Ballerup, Denmark) twice daily.[28] For the total severity score (a sum of scores of erythema, desquamation and plaque, rated from 0–3), mean improvement with clobetasol propionate exceed that of calcipotriene by 0.75 points after two weeks (P<0.001) and by 0.51 points after four weeks (P=0.028). For psoriasis global severity (rated on a scale of 0 to 5), clobetasol propionate shampoo was again associated with significantly greater improvement after two weeks (mean difference of 0.67 points between the clobetasol propionate and calcipotriene groups; P<0.001) and after four weeks (mean difference of 0.43 points; P=0.016).[28] Both treatments also improved erythema, plaque thickening, adherent desquamation and pruritus, and these effects were more pronounced in patients receiving clobetasol propionate shampoo.[28] After four weeks, 50% of patients in the clobetasol propionate group and 28.4% of patients in the calcipotriene group were rated by investigators as "clear" or "almost clear" of psoriasis (P=0.003). Similarly, patient self-report revealed that 47.3% of patients treated with clobetasol propionate and 31.1% of patients treated with calcipotriene were "clear" (P=0.009; Figure 2). Clobetasol propionate shampoo was well tolerated, with subjects reporting fewer adverse events than with calcipotriene.[28] One patient in the clobetasol group experienced a treatment-related adverse event (folliculitis), compared with 17 patients with calcipotriene (including dermatitis, erythema, desquamation, eczema, pruritus and irritation of the skin and nails).[28]

Griffiths and colleagues performed a randomized, investigator-blinded trial that enrolled 162 patients with scalp psoriasis who applied either 0.05% clobetasol propionate shampoo once daily or 1% tar blend shampoo (Polytar Liquid®, Stiefel Laboratories [UK] Limited, Berkshire, UK) weekly.[29] Patients using clobetasol propionate experienced a 50% reduction in psoriasis severity

FIGURE 1. Percent of subjects with no or mild signs and symptoms at the end of treatment. Outcomes were significantly in favor of clobetasol propionate shampoo after four weeks of treatment (all P<0.001).[3] Reprinted with permission from: Jarratt MT, Breneman D, Gottlieb AB, Poulin Y, Liu Y, Foley V. Clobetasol propionate shampoo 0.05%: A new option to treat patients with moderate to severe scalp psoriasis. J Drugs Dermatol. 2004:3:367-373.



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after four weeks, compared to a reduction of 14.5% with tar shampoo.[29] Total Severity Score (TSS) was calculated as the sum of scores for erythema, desquamation and plaque thickening (scales 0–9). At weeks two and four, clobetasol propionate shampoo treatment was superior to tar shampoo for a rating scale of psoriasis symptoms, and for a global psoriasis assessment (P=0.0001) (Figure 3).[29] Clobetasol propionate shampoo also produced significantly greater improvement in erythema, plaque thickening, desquamation, and pruritus, as well as a reduction in total scalp area affected by psoriasis and greater patient-reported improvement.[29] Mild-to-moderate adverse events (e.g., scalp itching, stinging, burning) occurred more often with clobetasol propionate shampoo (8%) than with coal tar shampoo (3%), but only one subject (clobetasol group) withdrew from the study due to adverse events.[29]

FIGURE 2. Investigator and patient assessments of improvement were significantly higher in the clobetasol propionate-treated subjects (ITT population, at week 4).[28] a) Investigator assessment: at week 4, the scalp psoriasis was considered almost cleared. b) Subject assessment: at week 4, the scalp psoriasis was considered almost clear.
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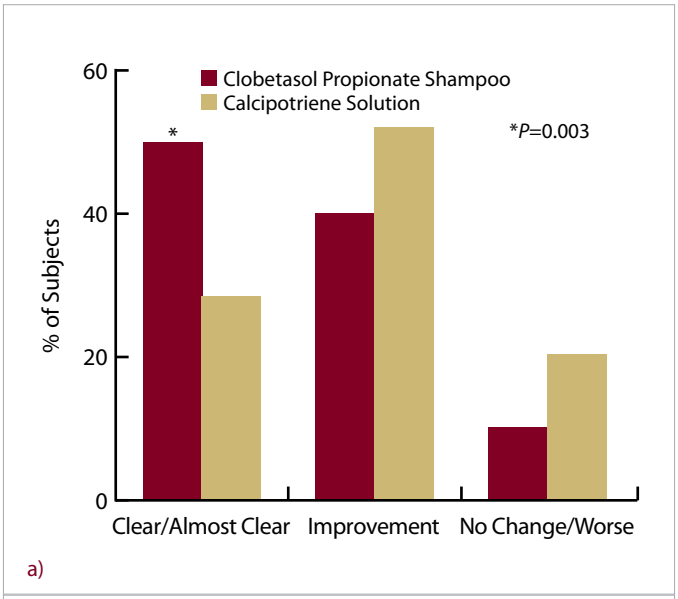

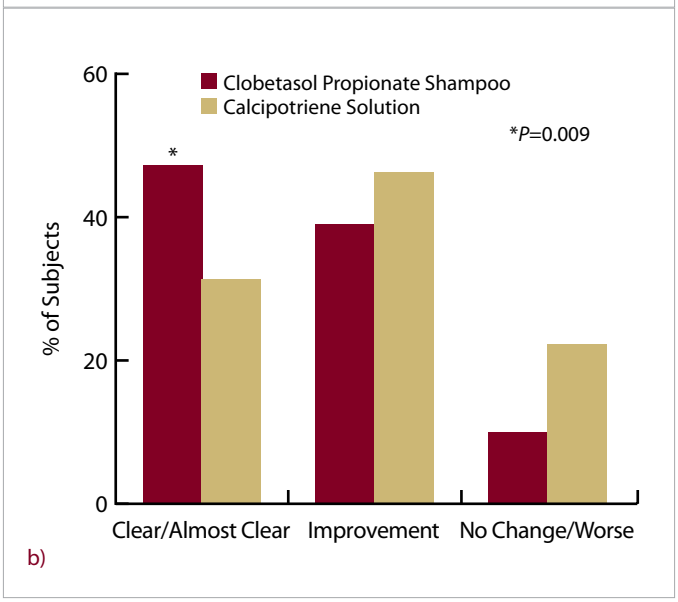

Shampoo Therapy for Seborrheic Dermatitis

The two principal treatment options for seborrheic dermatitis are topical corticosteroids and topical antifungal agents, both of which are available in shampoo formulations.[30]

The antifungal agents ketoconazole, selenium sulfide, and zinc pyrithione have long been used to treat seborrheic dermatitis and all are available in shampoo formulations for the treatment of seborrheic dermatitis of the scalp.[31] In 2003, a shampoo formulation of the topical antifungal agent ciclopirox (ciclopirox 1 % shampoo; Loprox® Shampoo, Medicis, Scottsdale, AZ) was approved in the U.S. In two clinical trials lasting four to six weeks conducted in Germany, ciclopirox 1% shampoo pro-

FIGURE 3. Clobetasol propionate shampoo treatment was superior to tar shampoo for a rating scale of psoriasis symptoms, and for a global psoriasis assessment, at weeks 2 and 4 (P=0.0001).[29]
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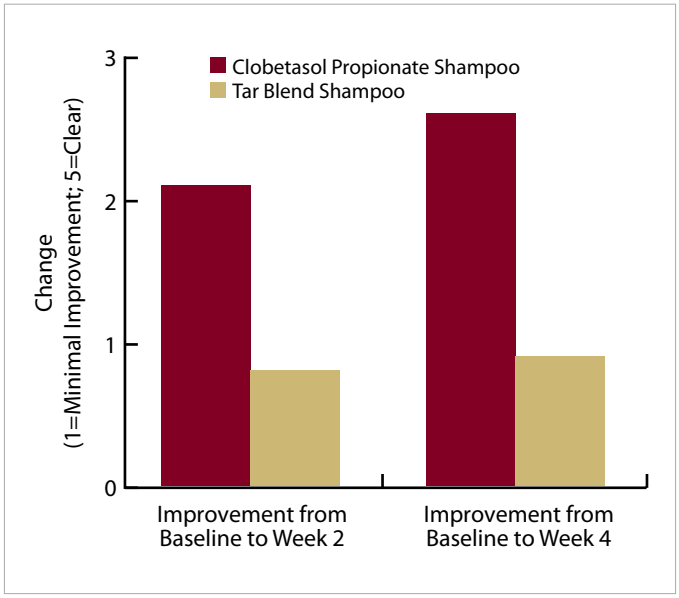

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duced treatment responses (defined as posttreatment seborrheic dermatitis severity of "none" or "slight") in approximately 60–67% of patients, compared with 32–38% of patients who received vehicle shampoo.[7,32] Lower ciclopirox concentrations (0.1% or 0.3%) did not improve seborrheic dermatitis symptoms. A randomized, double-blind clinical trial of 499 patients with seborrheic dermatitis conducted in the U.S. also found that ciclopirox 1% shampoo was more effective than vehicle shampoo.[33] Treatment success was defined as a posttreatment rating of no seborrheic dermatitis (or slight seborrheic dermatitis for patients with moderate to severe disease at baseline).[33] Application of ciclopirox 1% shampoo twice weekly for 4 weeks produced a treatment success rate of 42.4%, compared with a success rate of 24.1% for patients who received vehicle shampoo (P<0.001).[33] A multicenter, randomized clinical trial of 949 patients with seborrheic dermatitis of the scalp in Europe found that once-weekly shampooing with ciclopirox 1% shampoo prevented the recurrence of seborrheic dermatitis in more than 85% patients who responded to initial therapy.[34]

A recent study that compared the efficacy and safety of ciclopirox 1.5% shampoo versus ketoconazole 2.0% shampoo (Nizoral®, McNeil Consumer Healthcare, Fort Washington, PA) found that both agents produced significantly greater improvement than placebo shampoo in seborrheic dermatitis of the scalp.[35] Patient assessments of individual symptoms (e.g., itching, scaling) for both active treatment groups were superior to placebo shampoo, as were ratings of global improvement by clinicians. The ketoconazole and ciclopirox shampoo groups did not differ significantly from one another for these evaluations. However, patient assessment of overall signs and symptoms indicated significantly greater improvement from baseline with ciclopirox shampoo than with ketoconazole shampoo (P=0.03).

A shampoo formulation containing the corticosteroid fluocinolone acetonide, 0.01% (Capex® Shampoo, Galderma Laboratories, L.P., Ft. Worth, TX) is approved for the treatment of seborrheic dermatitis. In a randomized, double-blind, multicenter clinical trial of 100 patients with seborrheic dermatitis of the scalp, fluocinolone acetonide, 0.01% shampoo produced marked to complete clearing in 84% of patients after 14 days of treatment, compared with 28% of patients who were treated with vehicle shampoo.[36] Although patient selection criteria and outcome measures have varied somewhat from study to study, in this clinical trial, the response rate observed with fluocinolone acetonide shampoo appears to compare favorably with response rates described previously in studies that examined antifungal agents for this indication. This corticosteroid shampoo produced significantly greater improvement from baseline in rating scale scores for erythema, scaling and pruritus. Erythema improved from baseline by a mean of 80% versus 43% for the corticosteroid shampoo group and placebo groups, respectively; scaling was reduced by 76% versus 44%; and pruritus was reduced by 82% versus 68% (P<0.001 for each comparison).[36]

The efficacy and safety of clobetasol propionate shampoo for the treatment of seborrheic dermatitis of the scalp were recently evaluated in a pilot study of 55 patients.[27] This multicenter, investigator-blinded study was designed to test the hypothesis that once-daily treatment with a short-contact, high-potency corticosteroid would improve seborrheic dermatitis with a low risk of corticosteroid-related adverse events.[27] Patients were randomized to one of five treatment groups: clobetasol propionate 0.05% shampoo applied for 2.5, 5 or 10 minutes; vehicle shampoo applied for 10 minutes; or ketoconazole foaming gel 2% for five minutes.[27] Each of the treatments was applied twice weekly to wet hair for up to four weeks.[27] Erythema and desquamation were rated on a 7-point scale (from 0–3, including half points), and pruritus was evaluated by patients using a 100-mm analog scale. Global improvement from baseline was rated by the investigators on a 7-point scale from -1 (worse) to 5 (clear).[27] After four weeks, the mean improvement from baseline in total severity (calculated from ratings of erythema and desquamation) score was greater than 75% for each of the active treatment groups, compared with a mean improvement of 17.4% for the vehicle group (Figure 4). Each of the active groups produced significantly greater improvement from baseline than vehicle (P<0.01).[27] Compared with vehicle, significantly greater improvement in erythema was noted for the clobetasol

FIGURE 4. Mean improvement from baseline in total severity score (calculated from ratings of erythema and desquamation)[27] *P<0.01 versus vehicle.
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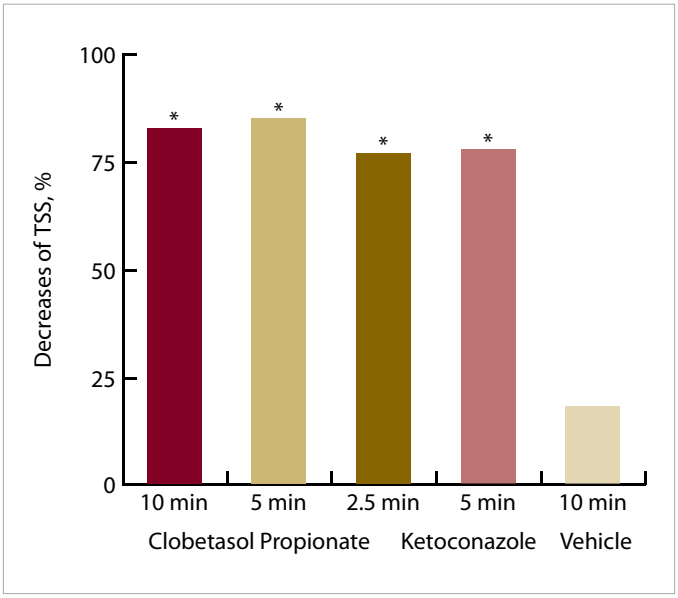

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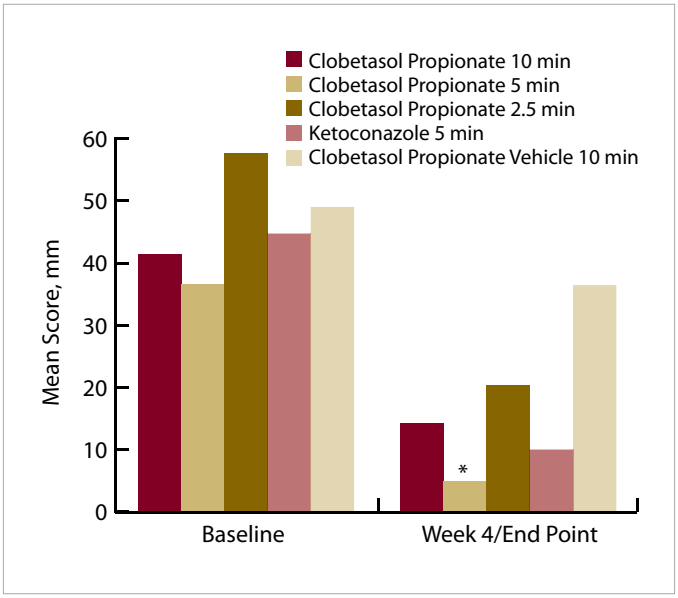
five-minute and ketoconazole groups, and significantly greater improvement in pruritus was noted only for the clobetasol five-minute group (Figure 5).[27] Complete clearance of seborrheic dermatitis after 4 weeks was noted for one of 11 patients (9.1%) in the ketoconazole and vehicle group, two of 11 patients (18.2%) in the clobetasol two-minute and five-minute group, and five of 11 patients (45.5%) in the clobetasol 10-minute group. All of the treatments were well tolerated. Treatment-related adverse events included dry skin (one patient in the clobetasol 10-minute group), folliculitis (one patient in the clobetasol five-minute group), and eczema (one patient in the vehicle group).[27]

Shampoo Therapy for Other Inflammatory Disorders of the Scalp

In addition to their effectiveness for seborrheic dermatitis, antifungal shampoos have also been used to treat other inflammatory fungal disorders affecting the scalp. For example, ketoconazole 2% shampoo is used in combination with oral antifungal therapy for the treatment of tinea capitis in children, and has been shown to reduce pruritus, scaling and erythema when used as monotherapy.[37] Ketoconazole shampoo was also evaluated for the treatment of pityriasis (tinea) versicolor, a chronic, recurring, superficial fungal infection that usually affects the upper trunk, neck, or arms.[13] Application of ketoconazole to affected skin and surrounding areas produced significantly greater treatment response rates than placebo shampoo in patients with tinea versicolor (approximately 70% of patients with ketoconazole shampoo versus 5% of patients with placebo), and significantly reduced symptoms of scaling, pruritus, and erythema.[38]

FIGURE 5. Compared with vehicle, significantly greater improvement in pruritus was noted only for the clobetasol 5 minute group. Pruritus was measured on a 100-mm analog scale.[27] *P<0.01 versus vehicle. Reprinted with permission from: Reygagne P, Poncet M, Sidou F, Soto P. Clobetasol propionate shampoo 0.05% in the treatment of seborrheic dermatitis of the scalp: Results of a pilot study. Cutis. 2007;79:397-403. ©2007, Quadrant HealthCom Inc.



CONCLUSION

Scalp lesions are common among patients with psoriasis, atopic dermatitis, seborrheic dermatitis and a number of other mycotic and inflammatory conditions. Inflammatory dermatoses involving the scalp are associated with considerable patient discomfort and distress, and are also especially challenging to treat due to limited patient acceptance of some topical treatment options because of the difficulty of use and the close proximity of sensitive facial skin. Topical corticosteroids are a mainstay of treatment for many inflammatory skin conditions, and considerable recent research has focused on new vehicles to improve the delivery of these agents for patients with scalp involvement. Medicated shampoos offer greater convenience for topical scalp therapy, and are effective for a range of inflammatory dermatoses affecting the scalp. Shampoos containing antifungal agents significantly improve seborrheic dermatitis in most patients, and are also used to treat a number of other mycotic conditions that involve the scalp. A shampoo formulation of the low-potency corticosteroid fluocinolone acetonide is also effective for the treatment of seborrheic dermatitis.

Despite the importance of both topical corticosteroids and shampoos in the treatment of inflammatory dermatoses, only one high-potency corticosteroid shampoo is approved for use in the U.S. Clobetasol propionate 0.05% shampoo is a safe and effective option for convenient once-daily corticosteroid therapy for scalp inflammation. In patients with moderate to severe scalp psoriasis, clobetasol propionate shampoo produced clearing or minimal residual psoriasis after four weeks in more than 40% of patients, compared with 2% of patients who received vehicle shampoo.[3] In a pilot study, clobetasol propionate shampoo also improved the signs and symptoms of seborrheic dermatitis. These results suggest that clobetasol propionate shampoo may also be effective for the treatment of other inflammatory conditions of the scalp that are currently treated using conventional topical corticosteroid formulations.

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