# Clobetasol Propionate Spray 0.05% for the Treatment of Moderate to Severe Plaque Psoriasis

Alan Menter, MD

Clobetasol propionate is a super-high potent class 1 topical corticosteroid available in several formulations, including a spray formulation that is approved for use up to 4 weeks in patients aged 18 years and older with moderate to severe plaque psoriasis. The efficacy and safety of clobetasol propionate spray 0.05% has been extensively evaluated in clinical trials in more than 2200 patients with moderate to severe plaque psoriasis. This article reviews the efficacy, safety, and tolerability of clobetasol propionate spray 0.05%. Clobetasol propionate spray 0.05% is a topical product with a documented efficacy and safety profile with good acceptability in patients with moderate to severe plaque psoriasis.

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soriasis affects approximately 2% to 3% of the US population, causes substantial psychological and social distress, and impairs health-related quality of life in patients with the disease.<sup>1-3</sup> The impact of the disease on physical and mental functioning is comparable to patients with arthritis, cancer, depression, diabetes mellitus, heart disease, and hypertension.<sup>2</sup>

Effective topical and systemic therapy is available for psoriasis.<sup>4</sup> Topical therapy is useful across the full spectrum of disease severity (ie, mild to severe) either

3900 Junius St, Ste 145, Dallas, TX 75246 (amderm@gmail.com).

as monotherapy or in combination with phototherapy, systemic therapy, or biologic therapy for patients with more widespread disease. Patients with mild disease of limited extent (<5% body surface area [BSA]) may respond to short-term treatment with a lowerpotency corticosteroid, whereas those with moderate to severe disease (>5% BSA) typically require a more potent corticosteroid, such as clobetasol propionate, to achieve adequate control. Approximately 80% of patients with psoriasis have mild to moderate disease and most of these patients can be treated (safely and effectively) with topical agents.<sup>4</sup>

Adherence to prescribed therapy plays an important role in the success of topical agents for psoriasis.<sup>5</sup> Unfortunately, the results of patient surveys show that approximately 40% to 60% of patients are nonadherent with their prescribed topical therapy.<sup>6-9</sup> According to these studies, factors that may influence adherence include the choice of vehicle, therapeutic response, tolerability, extent of disease, and patient education. Patients with the greatest risk for poor adherence include those who feel inconvenienced by their medication or frustrated with the efficacy of treatment as well as those who are fearful of side effects.<sup>4</sup> Another survey showed that patient fear of potential side effects contributes more to nonadherence than the experience of actual side effects. The same survey showed that the most prominent reasons for nonadherence with a topical corticosteroid regimen were lack of efficacy, staining of clothes, timeconsuming application, and interference with daily activities.<sup>9</sup> Adherence with therapy for psoriasis also has been shown to be negatively correlated with quality of life.<sup>8</sup>

To improve adherence, the American Academy of Dermatology guidelines of care for the management and treatment of psoriasis with topical therapy

From the Baylor Psoriasis Research Center (Baylor Research

Institute), Baylor University Medical Center, Dallas, Texas. Dr. Menter is a consultant and speaker and is on the advisory board

for Galderma Laboratories, LP. Correspondence: Alan Menter, MD, Baylor University Medical Center,

encourage the use of topical medications with sufficient potency to achieve a favorable response and individualization of the vehicle to improve patient acceptance.<sup>4</sup> Thus the choice of vehicle has a considerable impact on patient adherence and quality of life. Although the choice of vehicle should be tailored to individual patient preferences, there are data suggesting that patients generally prefer solutions and foams over creams, gels, and ointments, largely based on characteristics such as ease of application, time needed for application, and messiness.<sup>10</sup> Furthermore, the use of a foam has been associated with better quality of life compared to use of the combination of a cream and lotion.<sup>11</sup>

Topical corticosteroids are the cornerstone of topical therapy for most patients with psoriasis. Among topical corticosteroids, clobetasol propionate is the most commonly used agent in the United States.<sup>4,12</sup> Clobetasol propionate, produced in 1973, is a superhigh potent class 1 topical corticosteroid, more recently available in several formulations, including a spray formulation. The spray formulation is the only such topical product approved for use up to 4 weeks for the treatment of moderate to severe plaque psoriasis. The objective of this review is to evaluate the efficacy, safety, and tolerability of clobetasol propionate spray 0.05% when used for up to 4 weeks in patients with moderate to severe plaque psoriasis.

#### **Clinical Studies**

Clobetasol propionate spray 0.05% has been evaluated in randomized, vehicle-controlled, double-blind studies with a treatment duration of up to 4 weeks,<sup>13-16</sup> and in a head-to-head, randomized study in which it was compared with calcipotriene-betamethasone dipropionate ointment.<sup>17</sup> The product also has been evaluated as monotherapy and add-on therapy with both topical and systemic antipsoriatic agents in a large multicenter, open-label, observational trial (Clobex<sup>®</sup> Spray Community-Based Research Assessment [COBRA]).<sup>18,19</sup>

### **Comparisons With Vehicle**

The efficacy and safety of clobetasol propionate spray 0.05% in patients with moderate to severe plaque psoriasis was established in four 4-week double-blind, vehicle-controlled studies.<sup>13-16</sup> One study evaluated patients with moderate to severe plaque psoriasis of the scalp. Patients with psoriasis lesions on both the scalp and body were eligible for this trial provided that the extent of overall involvement was 20% of BSA or less.<sup>16</sup>

The first trial evaluated 27 adults with bilateral plaques affecting an area of 5 to 100 cm<sup>2</sup> and a plaque severity score of at least 5 (moderate to severe) on a collapsed 9-point scale (0-1=none;2-3=mild; 4-5=moderate; 6-7=severe; 8=very severe).<sup>13</sup> Patients served as their own controls in this intra-individual study in which individual lesions were randomized to treatment with either clobetasol propionate spray 0.05% or vehicle. The mean plaque severity score was significantly lower for lesions treated with clobetasol propionate spray 0.05% compared with vehicle at all postbaseline time points (P<.01). After 2 weeks of treatment, 80% (20/25) of lesions treated with the active spray formulation were assessed as none (0-1) or mild (2-3) on the 9-point assessment scale compared with 16% (4/25) of lesions treated with vehicle. After 4 weeks of treatment, 100% (25/25) of lesions treated with the active spray formulation were assessed as none or mild compared with 28% (7/25) of vehicle-treated lesions. Improvement in individual scores for scaling, erythema, and plaque elevation were consistently greater for lesions treated with clobetasol propionate spray 0.05% compared with those treated with vehicle.<sup>13</sup>

Clobetasol propionate spray 0.05% was next evaluated in 2 larger multicenter, randomized, doubleblind, vehicle-controlled trials of identical design.<sup>14,15</sup> Both trials enrolled 120 participants with moderate to severe plaque psoriasis affecting at least 2% BSA and a target lesion severity of at least 3 (moderate) on a 5-point scale (0=none; 4=severe/very severe) who were randomly assigned to 4 weeks of twicedaily treatment with the active spray formulation or vehicle spray. Treatment success was defined using the 5-point scale, but it is important to note that the definition of success was more stringent at week 4 (0 [clear] or 1 [almost clear]) than at week 2 (0 [clear], 1 [almost clear], or 2 [mild]).<sup>14,15</sup>

In the first of the larger studies, significant improvement was evident after 1 week of treatment (P < .01), and the proportion of participants with total clearing (clear or almost clear disease) increased from week 2 to week 4 (Figure 1). Significantly more participants randomized to clobetasol propionate spray 0.05% had clear or almost clear lesions compared with vehicle after both 2 weeks (55% [33/60] vs 2% [1/60]; P<.001) and 4 weeks (78% [47/60] vs 3% [2/60]; P<.001) of treatment in this study. Of note, the percentage of clobetasol propionate-treated participants with total clearing of lesions increased from 2% (1/60) at week 2 to 25% (15/60) at week 4.14

These results were confirmed in a second study of similar design in which higher success rates among recipients of clobetasol propionate spray 0.05% were observed after 2 and 4 weeks of treatment. After 4 weeks of treatment, the proportion of participants achieving treatment success was 82% (49/60) in

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**Figure 1.** Participants with clear or almost clear disease after 2 and 4 weeks of treatment with clobetasol propionate spray 0.05% in a randomized, vehicle-controlled trial. Reprinted with permission from *Cutis.* 2006;78:348-354. ©2006, Quadrant HealthCom Inc.<sup>14</sup>

the clobetasol propionate spray 0.05% group and 2% (1/60) in the vehicle-treated group.<sup>15</sup>

Safety also was evaluated in the Jarratt et al<sup>14</sup> study by specific tolerability queries (eg, skin atrophy, telangiectasia, burning/stinging, and folliculitis) as well as by general reports of clinical signs and symptoms of hypothalamic-pituitary-adrenal axis suppression. The only queried adverse event reported during treatment was burning/stinging by 14 (23%) participants treated with the active spray formulation and 13 (22%) participants treated with vehicle. The severity of this event was most often mild and the incidence decreased throughout the study. No clinical sign of hypothalamic-pituitary-adrenal axis suppression was detected during the study.<sup>14</sup>

In the study in patients with moderate to severe plaque psoriasis of the scalp, 81 patients were randomized up to 4 weeks of treatment with clobetasol propionate spray 0.05% (n=41) or vehicle (n=40).<sup>16</sup> In this trial, patients who achieved a rating of clear at week 2 were considered to have completed the study. The proportion of patients with a global severity scale rating of clear or almost clear was significantly higher in the active treatment group compared with vehicle after 2 weeks (80% [33/41] vs 8% [3/40]) and 4 weeks of treatment (85% [35/41] vs 13% [5/40]; P < .001)(Figure 2). In addition, the proportion of patients who achieved a rating of clear increased from 12% (5/41) after 2 weeks to 51% (21/41) after 4 weeks of treatment with clobetasol propionate spray 0.05%. The distribution of individual sign scores for psoriasis (ie, scaling, erythema, and plaque



**Figure 2.** Proportion of patients with plaque psoriasis of the scalp who met the criteria for treatment success (clear or almost clear) after 2 weeks and at the end of treatment. Figure was originally published in *J Drugs Dermatol.* 2011;10:885-892. Reproduced, with permission, from the *Journal of Drugs in Dermatology* ©2011.<sup>16</sup>

elevation) also were significantly different at both weeks 2 and 4 between individuals randomized to active treatment compared with vehicle (P < .001). Similarly, the distribution of pruritus severity scores at the end of treatment was significantly different (P < .001) between treatment groups: 68% (28/41) of patients treated with clobetasol propionate spray 0.05% reported no pruritus compared with 20% (8/40) of vehicle-treated patients; conversely no recipients of the active treatment (0/41) reported severe pruritus compared with 10% (4/40) of patients treated with vehicle. Finally, the extent of scalp involvement at the end of treatment was significantly reduced among recipients of clobetasol propionate spray 0.05% compared with recipients of the vehicle (*P*<.001).<sup>16</sup>

Mild skin atrophy was reported in 1 (3%) patient in the vehicle spray group, and mild telangiectasia was reported in 1 (2%) patient in the clobetasol propionate spray 0.05% group.<sup>16</sup> Stinging/burning was reported by 23 (58%) patients in the vehicle spray group (15 mild; 7 moderate; 1 severe) versus 11 (27%) patients in the clobetasol propionate spray 0.05% group (10 mild; 1 moderate). No serious adverse events or cases of Cushing syndrome were reported during the study.<sup>16</sup>

The results of these vehicle-controlled studies demonstrated that the spray formulation is highly effective and well-tolerated in patients with moderate to severe plaque psoriasis, including lesions located on the scalp, with the approved 4-week treatment regimen resulting in greater improvement than 2 weeks of treatment.<sup>13-16</sup>

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#### Comparison With Calcipotriene-Betamethasone Dipropionate Ointment

Clobetasol propionate spray 0.05% also has been compared with the combination of a topical vitamin D analogue and calcipotriene 0.005%– betamethasone dipropionate 0.064% ointment in a multicenter, open-label, randomized, parallel-group study in patients with stable, moderate to severe plaque psoriasis involving 3% to 20% BSA (mean BSA involvement at baseline was approximately 9%–10%). Patients were randomly assigned to the US Food and Drug Administration–approved dosage regimens: twice-daily treatment with the spray formulation or once-daily application of the ointment formulation for up to 4 weeks.<sup>17</sup>

Treatment success was defined as a rating of clear or almost clear disease (0 or 1 on the 5-point overall disease severity scale).<sup>17</sup> More patients in the perprotocol population (n=93) treated with clobetasol propionate spray 0.05% had a successful treatment outcome after 2 weeks of treatment compared with calcipotriene–betamethasone dipropionate ointment (41% [18/44] vs 27% [13/49]) and 4 weeks (75% [33/44] vs 45% [22/49]; P=.003)(Figure 3A). After 4 weeks of follow-up (study week), 14% (6/44) of clobetasol propionate spray 0.05%–treated patients and 8% (4/49) of calcipotriene–betamethasone dipropionate ointment–treated patients still met the definition of treatment success.<sup>17</sup>

The trend in investigator global assessment (IGA) scores was similar.<sup>17</sup> The IGA was a secondary end point in the trial and was based solely on the involved

BSA with no assessment of plaque characteristics or severity, thus representing a less comprehensive assessment of involved plaques than the overall disease severity scale. Success on the 4-point IGA scale was defined as a score of clear (0) or mild (1). More recipients of clobetasol propionate spray 0.05% than calcipotriene-betamethasone dipropionate ointment achieved the criteria for treatment success at weeks 2 (52% [23/44] vs 33% [16/49]) and 4 (73% [32/44] vs 65% [32/49]), and after 4 weeks of follow-up (41% [18/44] vs 24% [12/49]); however, none of these differences were statistically significant (Figure 3B). There was no statistically significant difference in quality-of-life scores, as measured by the psoriasis quality of life questionnaire, between the 2 groups at weeks 2 or 4 of treatment. However, a survey completed by patients in the trial showed that recipients of the spray formulation were more satisfied with their treatment compared with the ointment with respect to ease of application (P < .001), personal appearance (P=.014), treatment results (P=.03), comparison with prior treatments (P=.015), the desire to use their treatment in the future (P < .001), ease of absorption into the skin (P < .001), and whether the product stained their clothing (P=.005). The only survey question for which the response significantly favored calcipotriene-betamethasone dipropionate ointment was whether patients experienced stinging, burning, or irritation related to treatment (P=.024 vs clobetasol propionate spray 0.05%).<sup>17</sup>

Both treatments were generally well-tolerated by patients. Three patients experienced severe stinging



**Figure 3.** Comparative efficacy of clobetasol propionate spray 0.05% or calcipotriene 0.005%–betamethasone dipropionate 0.064% ointment in patients with plaque psoriasis enrolled in a randomized trial, including the percentage of patients with treatment success as defined by overall disease severity (A) and investigator global assessment (B). Figure was originally published in *J Drugs Dermatol.* 2009;8:52-57. Reproduced, with permission, from the *Journal of Drugs in Dermatology* ©2009.<sup>17</sup>

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or burning among the clobetasol propionate spray 0.05% treatment group versus 1 patient in the calcipotriene–betamethasone dipropionate ointment treatment group (P=.016); however, there was no significant difference between treatments in the severity of erythema, peeling/scaling, or dryness.<sup>17</sup>

## Effectiveness in Clinical Practice Settings (COBRA)

The clinical effectiveness of clobetasol propionate spray 0.05% was investigated in the 4-week openlabel, observational COBRA trial.<sup>18,19</sup> Eligible patients with plaque psoriasis affecting 3% to 20% BSA received clobetasol propionate spray 0.05% twice daily for 4 weeks. Effectiveness was evaluated with a 6-point target plaque severity scale (0=clear; 5=very severe) and a 7-point investigators' global assessment of improvement scale (0=completely cleared; 6=worsened). Success on the target plaque severity scale was defined as a rating of 0 (clear) or 1 (almost clear), or an improvement in severity from baseline of at least 2 grades.<sup>18,19</sup>

The trial included patients who received clobetasol propionate spray 0.05% as topical monotherapy  $(n=1254)^{18}$  and as add-on therapy with other antipsoriatic agents (n=731).<sup>19</sup>

In the monotherapy arm of the COBRA study, the percentage of participants with target plaque severity ratings of clear and almost clear was 6.2% (78/1254) and 37.4% (469/1254), respectively, after 2 weeks of treatment, and 35.7% (448/1254) and 37.3% (468/1254), respectively, after 4 weeks of treatment.<sup>18</sup> At week 4, 80.0% (1003/1254) of participants achieved target plaque severity success (P<.001). The degree of improvement at week 4 was significantly relative to both baseline and week 2 (P<.001).<sup>18</sup>

The results of the investigators' global assessment of improvement analysis were similar.<sup>18</sup> At week 2, 30.2% (379/1254) of participants were rated as completely cleared or almost completely cleared. Improvement continued between weeks 2 and 4 with 69.3% (869/1254) of participants rated as completely cleared or almost completely cleared. This trend showed that improvement occurs quickly and continues throughout the entire 4-week treatment period. Less than 2% of participants showed no improvement at weeks 2 and 4.<sup>18</sup>

Treatment with clobetasol propionate spray 0.05% also produced significant improvement in quality of life (P<.001 vs baseline)<sup>18,19</sup> as assessed by 2 validated instruments: (1) Koo-Menter Psoriasis Instrument 12-question psoriasis quality of life, and (2) Dermatology Life Quality Index.<sup>20,21</sup> Consistent with this finding, the proportion of participants who

reported that they were very satisfied with treatment increased from 62.2% (780/1254) at week 2 to 76.3% (957/1254) at week 4.<sup>18</sup>

Participants in the add-on therapy arm of the trial were receiving ongoing topical or systemic antipsoriatic agents that were well-tolerated at baseline. On average, participants in this arm had a mean (standard deviation) BSA affected by psoriasis of 12.0% (6.12%) and had been receiving their existing therapy for 1 to almost 3 years before entering the study.<sup>19</sup>

At baseline, 51.3% (375/731), 38.0% (278/731), and 10.7% (78/731) of participants had target plaque severity ratings of moderate, severe, and very severe, respectively.<sup>19</sup> After 2 weeks of treatment with clobetasol propionate spray 0.05%, the proportion of participants with target plaque severity ratings of clear or almost clear, mild, and moderate was 40.8% (298/731),35.7% (261/731),and (153/731), respectively; after 4 weeks, 20.9% 69.9% (511/731) were clear or almost clear, 16.1% (118/731) were mild, and 6.7% (49/731) were moderate. In contrast, just 2.6% and less than 1.0% of participants had a target plaque severity rating of severe at weeks 2 and 4, respectively. Treatment success by target plaque severity criteria was achieved by 59.0% (431/731) of participants at week 2 and 80.3% (587/731) of participants at week 4 (both P<.001 vs baseline). Similarly, treatment success as determined by investigators' global assessment of improvement criteria (completely cleared or almost completely cleared) was achieved by 26.5% (194/731) of participants at week 2 and 62.0% (453/731) of participants at week 4. Quality of life improved significantly between baseline and week 4 visits (P<.001) on both instruments, and 94.0% (687/731) of participants were reported as being very satisfied or somewhat satisfied with their treatment.<sup>19</sup>

Clobetasol propionate spray 0.05% was welltolerated by patients receiving monotherapy and add-on therapy in the COBRA trial. Less than 1.0% of patients in the monotherapy and addon therapy arms of the trials withdrew from treatment because of adverse events.<sup>18,19</sup> After 4 weeks of treatment in the monotherapy arm of the trial, the incidence of moderate erythema, peeling/ scaling, dryness, and stinging/burning was 2.6%, 3.1%, 4.5%, and 2.0%, respectively.<sup>18</sup> Similarly, after 4 weeks of treatment in the add-on therapy arm of the trial, the incidence was 4.1%, 3.5%, 4.1%, and 1.6%, respectively.<sup>19</sup> Pruritus was reported by 5.7% of participants in the monotherapy arm and 6.3% of participants in the add-on therapy arm of the trial. The incidence of telangiectasia, skin atrophy, and folliculitis was approximately 1.0% in both arms of the

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trial.<sup>18,19</sup> Only 1 serious adverse event reported during the COBRA trial was considered to be possibly or probably related to treatment (a subcutaneous abscess that was subsequently determined to have been present prior to the commencement of therapy with clobetasol propionate spray 0.05%).<sup>19</sup>

### Conclusion

The efficacy and safety of clobetasol propionate spray 0.05% has been extensively evaluated in clinical trials in more than 2200 patients with moderate to severe plaque psoriasis. Consistent across randomized controlled studies, treatment for the approved 4-week duration was associated with a successful outcome (clear or almost clear) in 75% to 85% of patients, with improved quality of life. In conclusion, clobetasol propionate spray 0.05% is a topical product with a documented efficacy and safety profile and is well-accepted by patients with moderate to severe plaque psoriasis.

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