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Topical Therapy of Psoriasis

In this Issue...

Psoriasis treatment can be complex at times and may engender frustration in patient and provider alike. Despite the emergence of novel and sophisticated biologic medications, topical therapy remains the cornerstone of psoriasis treatment, with the majority of psoriasis patients receiving topical therapy exclusively. The introduction of novel vehicles and combination topical medications are recent advances in topical therapy for psoriasis that add significantly to the armamentarium available to clinicians.

While topical medications for psoriasis have shown excellent efficacy in clinical trials, in practice similar results are not necessarily reproducible. There are several potential explanations for this discrepancy, though patient adherence is perhaps the most critical factor in successful outcomes—if a patient doesn't use the medication the chances of it working are small.

In this issue, we review recent trial data for some of the novel topical medications, and report on adherence data that provides insight into the patient behaviors that impact outcomes.

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Program Directors

Bernard A. Cohen, MD

Professor of Pediatrics and Dermatology and Director of Pediatric Dermatology, Johns Hopkins Children's Center
Baltimore, MD

Susan Matra Rabizadeh, MD, MBA

Department of Dermatology
Johns Hopkins Cosmetic Center at Greenspring Station
Baltimore, MD

Mark Lebwohl, MD

Professor and Chairman
Department of Dermatology
The Mount Sinai School of Medicine
New York, NY

Elizabeth Sloand, PhD, CRNP

Assistant Professor of Pediatric Nursing
The Johns Hopkins University
School of Nursing
Baltimore, MD

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GUEST AUTHORS OF THE MONTH



Commentary & Reviews:
Steven R. Feldman, MD, PhD
Professor
Dermatology, Pathology and
Public Health Sciences
Department of Dermatology
Wake Forest University
School of Medicine
Winston-Salem, North
Carolina



Commentary & Reviews:
Daniel Pearce, MD
Chief Dermatology Resident
Department of Dermatology
Wake Forest University
School of Medicine
Winston-Salem, North
Carolina

Guest Faculty Disclosures

Dr. Feldman disclosed that he has received grants for clinical research and educational activities from, has served as an advisor, consultant and speaker to, and has served as an investigator for Abbott, Amgen, Centocor, Galderma, Stiefel and Warner Chilcott.

Dr. Pearce has disclosed no relationship with commercial supporters.

Unlabeled/Unapproved Uses

The authors have indicated that there will be no reference to unlabeled or unapproved uses of drugs or products in this presentation.

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LEARNING OBJECTIVES

At the conclusion of this activity, participants should be able to:

- To discuss with colleagues the role of poor adherence to topical therapy on psoriasis treatment outcomes
- To describe to colleagues and patients the impact of novel vehicles and combination topical medications on patients' preferences for psoriasis treatments
- To discuss with colleagues and patients techniques to help improve outcomes of topical psoriasis treatment

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COMMENTARY

All dermatologists will see ample psoriasis over the course of their careers, and the majority of these patients are treated *primarily* with topical therapies. Certainly extensive and/or life-altering psoriasis deserves systemic treatment or phototherapy, and the presence of concomitant joint disease typically requires systemic treatment. However, topical medications, particularly corticosteroids, can be successfully utilized in all psoriasis patients, as they are highly effective, very safe, provide relief from symptomatic lesions, and, for those on systemic therapy, help minimize the exposure to systemic agents.

There are many factors that may affect the efficacy of topical preparations. Commonly discussed are the ability of an active agent to: 1) partition from the vehicle, 2) penetrate through the stratum corneum, and 3) bind its cytoplasmic receptor and exert effect on transcription, etc. One overlooked aspect of successful treatment is adherence; if a medication does not get taken out of the cabinet, the components of efficacy mentioned above are irrelevant. We know that dermatology patients frequently don't use medications as instructed (and frequently lie about it!).¹⁻²

Two of the most common approaches to the topical treatment of psoriasis are clobetasol propionate, and the use of a class I or II corticosteroid with calcipotriene or calcipotriol. Often, however, there seems to be a discrepancy between the robust efficacy seen in clinical trials and the limited effectiveness seen in clinical practice, a discord likely explained by patient behaviors.

Clobetasol is commercially available in at least 7 different vehicles; selection of the appropriate preparation is critical to getting close to the efficacy reported in clinical trials. The notion that ointments are a "more potent" delivery system is dogma that is refuted by the efficacy seen with some of the newer, non-occlusive preparations discussed herein and elsewhere.³ Far more important than the moisturizing properties of the vehicle is the patient's propensity to use the medication.

The ideal topical medication is technically easy to apply, not messy, and has a simple dosing regimen. Novel preparations of clobetasol in lotion (Clobex®), spray (Clobex®) and foam (Olux®) vehicles have evolved to address patient preferences in topical therapy. The stout efficacy of these preparations may in part be explained by enhanced adherence: psoriasis patients are known to prefer less messy preparations.⁴ A combination betamethasone dipropionate/calcipotriene ointment (Taclonex® in the US), has impressive efficacy with only once-daily application. As discussed herein, its efficacy is remarkable and may be due to intrinsic properties of the medication as well as the facile dosing regimen. And although not definitively proven, once-daily dosing is likely to lead to better adherence and subsequent efficacy.

Topical therapy is not without limitations. Traditionally, tachyphylaxis has been defined as decreasing response to a medication with increasing use. Perhaps a better definition is decreased response to a medication with *decreased* use. Patients that use their medication tend to get better, while those that do not tend not to improve.⁵ The original study reviewed herein by Carroll et al from 2004 looked at several measures of adherence to a prescribed regimen for psoriasis, and provides meaningful implications for clinical practice. Among the findings as to why efficacy in clinical trials does not always seem to extrapolate to clinical practice, one reason may be that in the "controlled" trial world there are motivated patients given explicit instructions, multiple follow up visits, and cash as part of the study. Therefore, these study subjects tend to use their medications better than do clinic patients.

In summary, when chosen properly, topical therapy for psoriasis is safe and cost-effective. Patients with chronic skin diseases generally want to get better and want to use their medication. We frequently ask much of them, by providing inadequate patient education, recommending complex regimens without taking patient preference into account, and not arranging follow-up that reinforces positive adherence. It is unreasonable to expect that a patient with psoriasis will not improve

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with 1 or 2 weeks of clobetasol therapy regardless of previous treatment failures. Perhaps by taking the time to understand the patient's vehicle preferences, and by scheduling short (1-2 weeks) follow-up visits, we can improve the outcomes of our psoriasis patients and strengthen the physician/patient relationship.

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CLOBETASOL PROPIONATE IN A DESIRABLE FOAM VEHICLE FOR THE TREATMENT OF NON-SCALP PSORIASIS

Lebwohl M, Sherer D, Washenik K, et al. **A randomized, double-blind, placebo-controlled study of clobetasol propionate 0.05% foam in the treatment of nonscalp psoriasis**. *Int J Dermatol*. 2002 May;41(5):269-274.

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Gottlieb AB, Ford RO, Spellman MC. **The efficacy and tolerability of clobetasol propionate foam 0.05% in the treatment of mild to moderate plaque-type psoriasis of nonscalp regions**. *J Cutan Med Surg*. 2003 May-Jun;7(3):185-192.

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Clobetasol propionate (CP) is a popular choice for the treatment of psoriasis, and the introduction of CP in a heat labile foam vehicle was a significant advancement and the first to be shown via clinical trial to be effective in the treatment of scalp psoriasis. It is perceived as cosmetically more elegant than drippy liquids or greasy ointments for many patients, especially in regions of hair bearing skin.

The 2 studies reviewed here sought to determine the efficacy and safety of CP foam in the treatment of non-scalp or traditional plaque type disease. Data were collected on 81 and 279 patients respectively with mild-to-moderate plaque type psoriasis in 2 randomized, double-blinded, vehicle controlled trials, one of which was multicenter. Treatment regimens were similar, with twice daily dosing for 2 weeks duration followed by a 2 week non-treatment phase to assess durability of the 2 week efficacy. Primary measures used were Investigator Global Assessment (IGA) at week 2 (or at the end of treatment) and week 4 follow-up. Investigators were asked to visually integrate all lesions and use a 7 point scale (Lebwohl et al) or a 6 point scale (Gottlieb et al) for the IGA assessment. Treatment success was defined as 0, 1 or 2 (Lebwohl) or 0 or 1 (Gottlieb). Secondary endpoints in both studies included Patient Global Assessment (PGA).

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Focusing on Intent to Treat (ITT) analyses, the Lebwohl study found that at 2 weeks there was a statistically significant improvement in those subjects treated with CP foam compared to vehicle, as measured by the IGA. Twenty-seven percent of subjects treated with CP foam were said to have “marked or better improvement,” representing a 0, 1, or 2 score on the 7-point scale. Significant improvement was maintained at the 4 week visit, at which time subjects had not received drug for 2 weeks. Similar findings were noted based on PGA.

In the Gottlieb study, a significantly larger number of patients (139) were randomized to receive CP foam. The results were again statistically significant in favor of the CP foam treated group compared to vehicle. However, the magnitude of the effect was much larger in Gottlieb’s study, with 68% of treated patients having an IGA of clear or minimal psoriasis present, representing a 0 or 1 score on the 6 point IGA scale. PGA confirmed the efficacy of CP foam.

While topical clobetasol propionate has been shown to be effective in any of the currently available delivery systems, in clinical practice, the most important predictor of the success of this agent may be the patients’ propensity to apply it. Although vehicle preference is individualized, CP foam is considered cosmetically appealing for many patients, providing ease of application, quick absorption, and minimal (if any) residue. Further, there is now an emollient-based preparation that may serve to minimize irritation from the alcohol based CP foam.

UNIQUE EFFICACY AND PATIENT BEHAVIORS WHEN USING A TWO-COMPOUND COMBINATION PRODUCT WITH BETAMETHASONE DIPROPIONATE AND CALCIPOTRIOL

Kragballe K, van de Kerkhof PC. **Consistency of data in six phase III clinical studies of a two-compound product containing calcipotriol and betamethasone dipropionate ointment for the treatment of psoriasis.** *J Eur Acad Dermatol Venereol.* 2006 Jan;20 (1):39-44.

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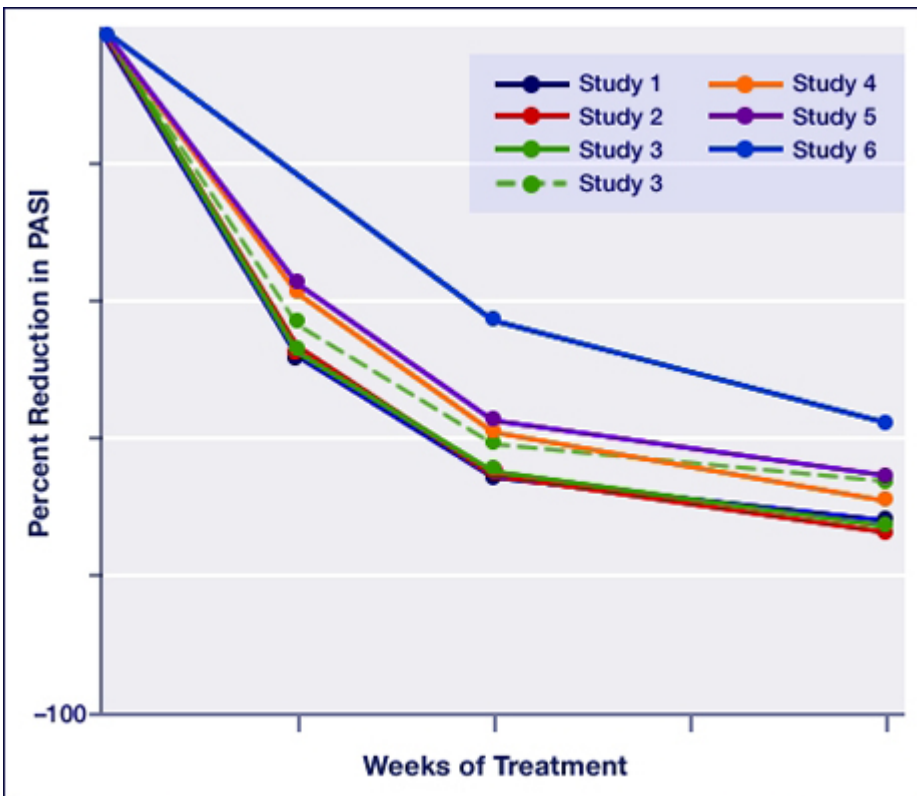
Kragballe and van de Kerkhof’s 2006 report compared the efficacy of the two-compound betamethasone dipropionate/calcipotriol (BC) ointment across multiple clinical trials. Six international, multicenter, randomized, blinded (all studies were reported to have an initial double-blinded phase) parallel-group studies with a total of 6050 patients were analyzed. Control group treatment varied slightly among the 6 trials, but 5 of the studies had betamethasone dipropionate and calcipotriol monotherapy groups. BC ointment was applied twice daily in 2 studies, once daily in 3 studies, and one study had both once and twice daily dosing groups. Each study was of a minimum 4 weeks duration, and all involved adults with plaque type psoriasis on more than 10% of body surface area. The primary outcome was the percentage Psoriasis Area and Severity Index (PASI) reduction measured in each study between baseline and weeks 2 and 4. In 5 of the 6 studies there was also a 1-week visit after starting treatment.

The range of mean PASI scores across the 6 trials ranged from 9.7 to 10.9. As shown in the graphic below, the effect seen in the BC ointment treated groups was remarkable.

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After 4 weeks of treatment, in subjects using a twice daily application protocol, mean PASI reductions were 73.2% to 74.4% (3 studies), while those in the once daily groups had a mean PASI improvement of 65% to 71.3% (4 studies). These data correspond to about 50% of subjects achieving a 75% improvement in PASI score (PASI75). Statistical significance was reached in each study, showing the improvement in BC ointment treated groups compared to the monotherapy calcipotriol and monotherapy betamethasone dipropionate groups. The most dramatic responses were seen in the first week, with a 38% to 48% PASI improvement of all the BC ointment-treated groups. There were multiple additional outcomes of interest in the varying studies, all of which showed superior outcomes in the BC ointment treated groups compared to controls. The adverse event profile of BC ointment was determined to be similar to betamethasone dipropionate and better than calcipotriol alone.

The authors have provided a valuable review of the efficacy of a novel preparation combining two accepted topical treatments for psoriasis. The fidelity of the data is attested to by the very similar results seen across the studies, leaving little doubt as to the superiority of BC ointment versus monotherapy with either constituent. One of the more interesting phenomena is illustrated in the figure above, and may highlight an important component of patient behavior: while the datapoints at week 2 are similar for all studies, there appears to be a small difference in the one trial that did not include a 1-week follow-up visit. A probable explanation for this difference is that study visits drive adherence to prescribed regimens – in practice, having more frequent visits is one way to help insure compliance. The thought of adhering to a regimen for a week or two is more feasible for many patients compared to a 3 or 6 month follow-up. This same principal serves alcoholics, as it is easier to quit drinking for one day at a time than for the rest of their lives all at once.

A NOVEL SPRAY FORMULATION OF CLOBETASOL PROVIDES EFFICACY AND SHORT TERM DURABILITY

Jarratt MT, Clark SD, Savin RC, et al. **Evaluation of the efficacy and safety of clobetasol propionate spray in the treatment of plaque-type psoriasis.** *Cutis*. 2006 Nov; 78(5):348-354.

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The article by Jarratt et al reports on the findings from the largest published “blinded” clinical trial for clobetasol propionate (CP) in a spray vehicle (Clobex® spray). The investigators sought to validate the efficacy of CP spray versus placebo in a multi-center, randomized, double-blinded, vehicle controlled, parallel-group study which enrolled a total of 120 subjects (60 in each group). CP spray or vehicle was applied twice daily to all active psoriasis plaques for 4 weeks, followed by a 4 week non-treatment phase. Evaluations occurred at weeks 1, 2, 4, and 8. Primary efficacy was measured using a 5 (0-4) point scale to rate scaling, erythema, plaque elevation, and pruritus, as well as overall severity. The primary endpoint was success defined dichotomously as mild, clear or almost clear (0, 1, or 2) for the overall severity measure at week 2. At week 4, a more stringent criteria of clear or almost clear (0 or 1) was used.

Most subjects were men, and 94% of subjects were white. After only 2 weeks of treatment, 87% of subjects in the CP spray group achieved treatment success ($p < 0.001$). At week 4, using more the more restrictive definition of treatment success (clear or almost clear), 78% of subjects achieved treatment success ($p < 0.001$). The percentage of patients defined as “clear” or “almost clear” (0 or 1) increased from 55% to 78% from week 2 to week 4. Success rates were reported to reach statistical significance after only 1 week of treatment in favor of the CP spray group. The durability of the CP spray treatment response was assessed at week 8, 4 weeks after the last application of CP spray (or vehicle). 44% of patients remained treatment successes in the CP spray treatment group ($p < 0.001$). Subjective patient assessment of signs and symptoms favored the CP spray, with statistical significance reached at week 1 and maintained throughout the treatment period. Burning was the only queried side effect, and was seen at similar rates in both the treatment and control groups (23% vs. 22%). No atrophy, folliculitis, telangiectasia, or evidence of adrenal suppression were noted.

This study presents some of the most robust efficacy data for a topical medication for psoriasis to date. Nearly 90% of patients were found to have mild disease or better after only 2 weeks of treatment. This is a dramatic degree of improvement that has not been seen with any of the systemic treatments for psoriasis!

Although most class I corticosteroids are approved for relative short term use (2 weeks or less), the investigators found significant benefit in treating for another 2 weeks. The authors note that there were no local adverse effects, and, although there was no measurement of hypothalamic-pituitary-adrenal axis function, they found no clinical signs or symptoms of adrenal suppression (though certainly there would be concerns with longer continuous use of the medication). The finding that nearly one-half of subjects remained successfully treated after 4 weeks of no treatment is also remarkable, given concerns for “rebound” flares with the use of corticosteroids for psoriasis.

The authors report that the results of this study correspond to their clinical experience showing that even the thickest psoriasis responds to CP spray. They further note that some patients clearly prefer the ease of application and elegance of a spray that does not leave messy residue on hands and clothing; patients use the less messy medication more frequently and achieve better results. While moisturizing the lesions may provide some degree of benefit, moisturization is not necessary for clearing psoriasis plaques. The key is to clear the inflammation. Systemic cyclosporine does not moisturize psoriasis plaques, but it is a very

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effective psoriasis treatment. By eliminating the inflammation, the psoriasis plaques clear. Topical clobetasol is a very effective anti-inflammatory. It can be used in a variety of vehicles. The drug is most effective when formulated in a vehicle that the patient will actually use.

OFFICE VISITS MAY ENHANCE OTHERWISE POOR ADHERENCE IN PSORIASIS PATIENTS

Carroll CL, Feldman SR, Camacho FT, Manuel JC, Balkrishnan R. **Adherence to topical therapy decreases during the course of an 8-week psoriasis clinical trial: commonly used methods of measuring adherence to topical therapy overestimate actual use.** *J Am Acad Dermatol.* 2004; Aug;51(2):212-216.

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As discussed throughout this issue, while there are very effective topical medications available for psoriasis, outside of clinical trials this efficacy is not typically reproducible. While there may be many reasons for this discrepancy, perhaps the most relevant is non-adherence. Clinical trial subjects tend to be highly motivated paid participants that are seen frequently and coached throughout the study; their adherence to a b.i.d. topical is expected to be higher than what is expected in practice. Studying adherence is tricky, as conventional approaches using weights and diaries tend to suffer from a variety of biases. In this study, Carroll et al set out to determine patient adherence to an 8 week treatment course using a twice daily dosed topical medication for psoriasis. The investigators employed a novel method of measuring adherence by fitting the medication bottles with an electronic monitoring cap that recorded the times the bottle was opened and closed. The data from these electronic monitors was then compared to patient medication logs and (at study visits) the weight of the remaining medication. Daily adherence was defined as the number of days a patient used the medication as instructed, and overall adherence was defined as the doses applied divided by the number of doses expected to be applied during the set interval. Visits were scheduled at weeks 1, 2, 4, and 8.

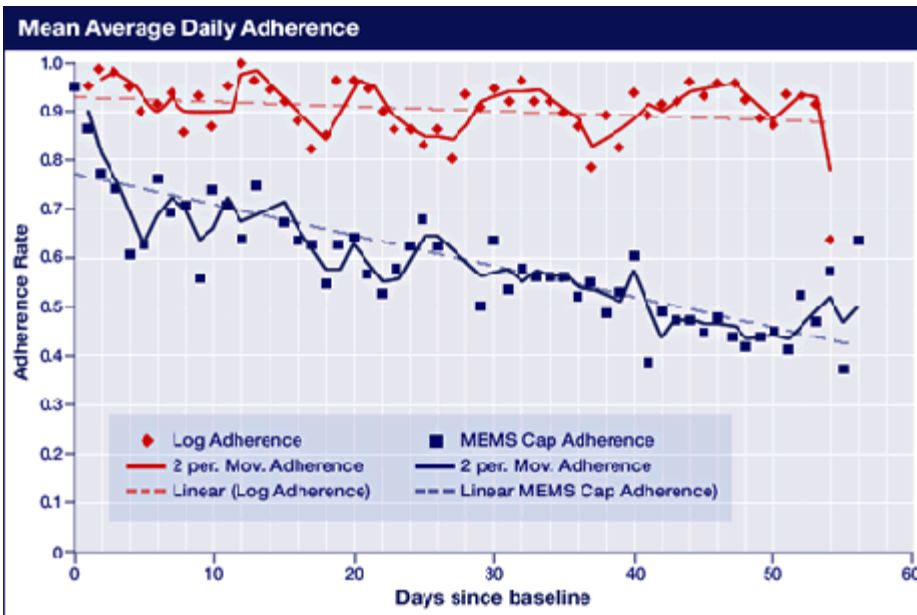
Complete adherence data (electronic, diaries and weights) were available for 21 of the 30 patients that were enrolled. Genders were represented equally, and 90% of patients were Caucasian. Overall adherence was 55% and the mean daily adherence was 39.1%. There was a statistically significant decline in adherence during the 8 week treatment period as measured by the electronic cap at study visits (85%, 77%, 67%, and 51%), while patient diaries reported a mean overall adherence of 90% that remained relatively constant. Interestingly, medication weights consistently reflected >100% adherence, implying that when the medication bottle was opened, a larger than recommended quantity of medication was applied. Women and increasing age predicted better adherence. The mean number of gaps in treatment of 24-48 hours and >48 hours were 7.6 and 3.1, respectively. The number and length of these gaps in treatment increased significantly as the study proceeded. Finally, there was increased adherence at the time of study visits.

These adherence data are graphically represented below:

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Adhering to a prescribed regimen can be difficult, and the impact of non-adherence to clinical practice is just beginning to be understood. In this study, patients were seen to use their medication less over time and to report significant over-usage (i.e. “lie”) in their logs. Likely this behavior is not out of spite or malingering/secondary gain, but rather the desire of the patient to please their provider. As seen here (and in other literature) adherence increases around the time of office visits and has been called the “dental floss effect.”

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Learning Objectives — [back to top](#)

At the conclusion of this activity, participants should be able to:

- To discuss with colleagues the role of poor adherence to topical therapy on psoriasis treatment outcomes
- To describe to colleagues and patients the impact of novel vehicles and combination topical medications on patients' preferences for psoriasis treatments
- To discuss with colleagues and patients techniques to help improve outcomes of topical psoriasis treatment

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- **Susan Matra Rabizadeh, MD, MBA** has disclosed no relationships with commercial supporters.
- **Mark Lebwohl, MD** has disclosed that he has received grants for clinical research and educational activities from, has served as an advisor, consultant and speaker to, and has served as an investigator for Abbott, Amgen, Astellas, Centocor, Genentech and Novartis.
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