

CLINICAL UPDATE

TOPIC HIGHLIGHTS

- **Combination Tazarotene and Clindamycin/Benzoyl Peroxide**
- **Use of Clindamycin 1%/Benzoyl Peroxide 5% Gel Alone and in Combination for Acne Vulgaris**
- **Patient Preference for Clindamycin/Benzoyl Peroxide Gel Formulations**
- **Quantitative Assessment of the Application and Consumption of Topical Acne Medication by Patients**
- **Sulfacetamide/Sulfur Combination With Sunscreen for Rosacea**

FACULTY

James Q. Del Rosso, DO, FAOCD
University of Nevada
School of Medicine
Las Vegas

Faculty and Unapproved Use Disclosures

Faculty must disclose any significant financial interest or relationship with proprietary entities that may have a direct relationship to the subject matter. The faculty must also disclose any discussion of investigational or unlabeled uses of products.

Dr Del Rosso has received funding for clinical grants from Galderma S.A., Intendis Inc., Mediciis Pharmaceutical Corporation, and Stiefel Laboratories, Inc. He is a consultant to Galderma, Intendis, and Stiefel. Dr Del Rosso discusses the use of metronidazole and azelaic acid as a once-a-day treatment for rosacea as opposed to twice daily.

Selected Issues in Dermatology

POSTER HIGHLIGHTS: FEBRUARY 18- 22, 2005, NEW ORLEANS, LOUISIANA

Trends in Dermatology Today

A *acne and rosacea are two of the most common disorders facing dermatologists today. The aim of this publication is to review important new trends in managing these prevalent and often challenging diseases.*

Acne vulgaris continues to be the most common dermatologic disorder, with approximately 85% of persons affected at some time between 12 and 24 years of age [*J Am Acad Dermatol.* 2003;49 (3 suppl):S200-S210]. It is most prevalent in adolescents, in whom there is an increase in androgen production [*Am J Clin Dermatol.* 2004;5:261-265]. Recent research has improved the understanding of acne pathophysiology, and it is well recognized that multiple factors are involved in its pathogenesis. The most notable pathogenic factors influencing acne development are (1) increased production of sebum, (2) abnormal follicular growth and differentiation, (3) proliferation of *Propionibacterium acnes* within the follicle, and (4) inflammation and immune response [*JAMA.* 2004; 292:726-735; *J Am Acad Dermatol.* 2003;49 (1 suppl):S1-S38].

Given the multifactorial nature of acne, a primary goal of therapy is to target as many pathogenetic events as possible while

maintaining acceptable safety and tolerability [*J Am Acad Dermatol.* 2003;49 (3 suppl):S199]. Combination therapy using agents with complementary mechanisms of actions is increasingly employed to accomplish this goal. A panel of acne clinicians and researchers recently suggested that combination therapy be initiated as early as possible, except in patients requiring oral isotretinoin [*J Am Acad Dermatol.* 2003;49(1 suppl):S1-S38].

The synergy between benzoyl peroxide and antibiotics in acne therapy has been well established, with several clinical trials documenting the safety and efficacy of topical benzoyl peroxide combinations with erythromycin or clindamycin [*J Am Acad*



James Q. Del Rosso, DO, FAOCD

President, Elsevier/IMNG
Alan J. Imhoff

**Vice President,
Medical Education &
Business Development**
Sylvia H. Reitman, MBA

**Program Manager,
Medical Education**
Sara M. Hagan

Graphic Design
Lehner & Whyte, Inc.

Production Specialist
Anthony Draper

This CLINICAL UPDATE was supported by an educational grant from



The supplement is based on a faculty interview and reviews of selected posters that were presented at a medical conference held February 18-22, 2005, in New Orleans, La.

The supplement was produced by the medical education department of International Medical News Group. Neither the Editor of PEDIATRIC NEWS, the Editorial Advisory Board, nor the reporting staff contributed to its content. The opinions expressed in this supplement are those of the faculty and do not necessarily reflect the views of the supporter or of the Publisher.

Copyright 2005 Elsevier Inc. All rights reserved. No part of this publication may be reproduced or transmitted in any form, by any means, without prior written permission of the Publisher. Elsevier Inc. will not assume responsibility for damages, loss, or claims of any kind arising from or related to the information contained in this publication, including any claims related to the products, drugs, or services mentioned herein.



**INTERNATIONAL
MEDICAL NEWS
GROUP**

Dermatol. 1983; 9:933-936; *J Am Acad Dermatol.* 1997;37:590-595; *Am J Clin Dermatol.* 2001;2:33-39]. The excipients in these formulations may also contribute to their effectiveness by enhancing skin barrier function, thereby counteracting potential for skin irritation. Glycerin and dimethicone are two such excipients that function as humectant and occlusive moisturizers, respectively. When used in a topical acne preparation, the synergistic properties of these moisturizing excipients may preclude irritation or the need for supplemental moisturizers.

Topical retinoids are generally considered a first-line therapy for mild acne, particularly comedonal acne with a few inflammatory lesions [*J Am Acad Dermatol.* 2003;49(1 suppl):S1-S38]. The addition of benzoyl peroxide with or without topical antibiotics to topical retinoids appears to speed the clearing of lesions, particularly in cases with a predominantly inflammatory component. Not only do such combination regimens target multiple areas of acne pathophysiology, but topical retinoids are also thought to alter skin permeability and enhance the penetration of topical antibiotics [*J Am Acad Dermatol.* 2003;49(1 suppl):S1-S38]. Oral antibiotics and topical retinoids are an effective combination for moderate to severe acne [*J Am Acad Dermatol.* 2003;49 (1 Suppl):S1-S38].

Rosacea is a common chronic disorder, affecting at least 14 million people in the United States [*Cutis.* 2004;73(1 suppl):4]. Despite advances in therapeutic interventions, the pathophysiology of rosacea has not progressed substantially and remains poorly understood [*J Am Acad Dermatol.* 2004;51:327-341]. Consequently, rational combination therapies have not been eval-

uated extensively in controlled trials. Therapeutic regimens are tailored according to disease subtype, with the combination of topical agents (metronidazole, azelaic acid, sulfacetamide/sulfur) and oral antibiotics (tetracyclines) forming the primary therapy for the papulopustular subtype [*Cutis.* 2004;74(suppl 3):21-27]. However, the effi-

cacy of combined topical agent combinations used for acne vulgaris, such as clindamycin/benzoyl peroxide, remains an unanswered question for patients with rosacea.

The following CLINICAL UPDATE summarizes selected clinical trials presented at a recent meeting of dermatology thought leaders held in

February 2005. These presentations reflect current trends in dermatology, with an emphasis on combination therapies for acne and rosacea management. The study conducted by Tanghetti et al demonstrates the benefits of combining clindamycin/benzoyl peroxide gel with the topical retinoid tazarotene, and Bikowski describes case reports of successful combinations in patients with varying severities of acne. Combination therapy for rosacea is addressed by Del Rosso, who describes successful clinical experience in combining sulfacetamide/sulfur with sunscreens with either topical metronidazole or azelaic acid.

Other reports focus on practical aspects of acne management. Del Rosso discusses the effects of vehicle type, application method, and patient education on compliance, efficacy, and longevity of a fixed amount of topical acne medication. Tanghetti et al report on the impact of product packaging and dosing regimen on patient preference for acne medication. The results of these studies illustrate that such practical considerations are significant components of optimal acne management.

Given the multifactorial nature of acne, a primary goal of therapy is to target as many pathogenetic events as possible while maintaining acceptable safety and tolerability.

Combination Tazarotene and Clindamycin/Benzoyl Peroxide

Topical retinoids such as tazarotene have established efficacy in acne management and are, to date, considered a first-line therapy for most patients [J Am Acad Dermatol. 2003;49(1 suppl):S1-S38; J Am Acad Dermatol. 2003;49(3 suppl):S200-S210]. Their primary mechanism of action is thought to be normalization of follicular keratinization and possibly enhancement of the follicular penetration of other agents [J Am Acad Dermatol. 2003;49(1 suppl):S1-S38; Acta Derm Venereol Suppl (Stockh). 1975; 74:111-115]. In contrast, antibiotics and benzoyl peroxide have antibacterial and anti-inflammatory activity that render them effective against both inflammatory and non-inflammatory acne [Acta Derm Venereol Suppl (Stockh). 1975; 74:111-115; J Am Acad Dermatol. 1997;37:590-595; Clin Ther. 2002;24:1117-1133]. Given these complementary actions,

it is rational that adjunctive use of antibiotics and benzoyl peroxide with a topical retinoid may provide greater clinical benefit than a topical retinoid alone.

...the combination of tazarotene and clindamycin/benzoyl peroxide gel achieved superior reduction in both open and closed comedones than did tazarotene alone...

Although several benzoyl peroxide/antibiotic combinations are available, they do not contain the same excipients that may contribute to clinical outcomes. Because topical retinoids can be irritating, consideration was given to the selection of a benzoyl peroxide/antibiotic combination

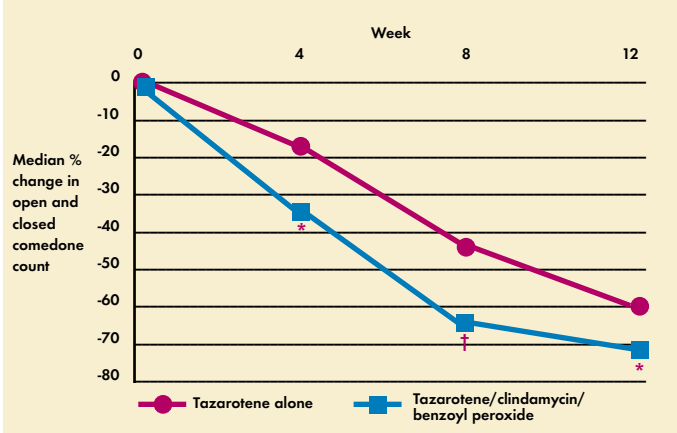
that may lessen irritation. A formulation of clindamycin 1%/benzoyl peroxide 5% is available that also contains 1% dimethicone and 4% glycerin. Dimethicone is an occlusive moisturizer that maintains epidermal barrier function by impairing evaporation of water into the atmosphere (Dermatol Clin. 2000;18:597-607). Glycerin is a humectant moisturizer that attracts water from the viable skin layers to the stratum corneum and may allow the skin to feel smoother [Dermatol Clin. 2000;18:597-607]. The combination of dimethicone and glycerin produces additive moisturizing properties and may obviate the need for supplemental moisturizers [Today's Ther Trends. 2003;21:269-275].

A multicenter, double-blind, randomized parallel-group study was conducted in 121 patients with moderate to severe facial inflammatory acne vulgaris to examine the

benefit of using clindamycin/benzoyl peroxide ready-to-dispense formulation in combination with tazarotene. Patients were randomized and instructed to receive tazarotene 0.1% cream each evening and either clindamycin 1%/benzoyl peroxide 5% gel or vehicle gel each morning for 12 weeks. Patients were instructed to apply a pea-sized amount of medication after washing their face with a non-soap cleanser and patting it dry with a soft towel.

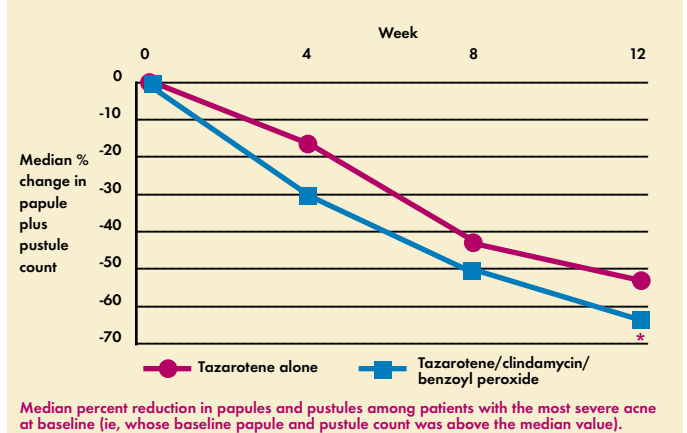
As depicted in Figure 1, the combination of tazarotene and clindamycin/benzoyl peroxide gel achieved superior reduction in both open and closed comedones than did tazarotene alone from week 4 to the study end. The tazarotene/clindamycin/benzoyl peroxide combination achieved median reductions of 34% and 70% at 4 weeks and 12 weeks, respectively, compared to 18% and 60% for

Figure 1. Reduction of Comedones in Patients With Moderate to Severe Facial Acne Vulgaris Receiving Tazarotene/Clindamycin/Benzoyl Peroxide vs Tazarotene Alone



* P ≤ 0.01, †P ≤ 0.001 vs tazarotene alone.

Figure 2. Reduction in Papules and Pustules in Patients With Severe Acne Receiving Tazarotene/Clindamycin/Benzoyl Peroxide vs Tazarotene Alone



Median percent reduction in papules and pustules among patients with the most severe acne at baseline (ie, whose baseline papule and pustule count was above the median value). * P ≤ 0.01 vs tazarotene alone.

Figure 3. Comparison of Facial Lesions at Baseline and After 8 and 12 Weeks of Tazarotene/Clindamycin/Benzoyl Peroxide Combination Therapy



Facial lesions of patient at baseline and after 8 and 12 weeks of receiving tazarotene/clindamycin/benzoyl peroxide combination therapy.

tazarotene alone ($P \leq 0.01$). Further, subanalysis of patients with the most severe acne at baseline demonstrated a greater reduction in papule and pustule count in patients receiving tazarotene/clindamycin/benzoyl peroxide than in those receiving tazarotene alone (63% vs 52%

at week 12, respectively; $P \leq 0.01$) (Figure 2 on page 3). Overall, the percentages of patients with a favorable or highly favorable impression of their study medication at week 12 were comparable between treatment groups (94% with tazarotene/clindamycin/benzoyl peroxide vs 90% with

tazarotene alone). Figure 3 illustrates the facial lesions of a patient at baseline and after 8 and 12 weeks of combination therapy with tazarotene/clindamycin/benzoyl peroxide.

Both regimens were well tolerated, with no significant differences between groups in the incidence of any treat-

ment-related adverse events. However, tazarotene in combination with clindamycin/benzoyl peroxide was associated with a lower incidence of peeling and dryness than was tazarotene alone (Table 1).

The results of this trial suggest that the combination of tazarotene plus clindamycin/benzoyl peroxide gel provides greater efficacy against acne, significantly faster clinical improvement, and less peeling and dryness than does tazarotene alone.

Based on: Tanghetti E, Abramovits W, Solomon B, Loven K, Shalita A. Tazarotene versus tazarotene plus clindamycin/benzoyl peroxide in the treatment of acne vulgaris: a multicenter, double-blind, randomized, parallel-group trial. Poster presented at: 63rd Annual Meeting of the American Academy of Dermatology; February 18-22, 2005; New Orleans, La. Abstract P147.

Table 1. Patients With Adverse Events Probably or Definitely Related to Study Treatment*

Adverse Event	Tazarotene Alone	Tazarotene/Clindamycin/Benzoyl Peroxide
Peeling	11 (18%)	6 (10%)
Burning	8 (13%)	8 (13%)
Redness/erythema	7 (12%)	8 (13%)
Dryness	7 (12%)	5 (8%)
Facial discomfort	2 (3%)	3 (5%)
Itching/pruritus	2 (3%)	3 (5%)
Oiliness	1 (2%)	1 (2%)
Facial irritation	0 (0%)	1 (2%)

*=There were no significant differences between groups for any event.

Use of Clindamycin 1%/Benzoyl Peroxide 5% Gel Alone and in Combination for Acne Vulgaris

The combination of clindamycin 1%/benzoyl peroxide has been proven to be a well-tolerated and effective option for acne vulgaris [*J Am Acad Dermatol.* 1997;37:590-595; *Am J Clin Dermatol.* 2001; 2:33-39]. Both clindamycin and benzoyl peroxide possess antibacterial activity, with use in combination providing additive benefit.

Six case studies of patients with acne who were successfully treated with topical clindamycin 1%/benzoyl peroxide 5% gel, alone and in combina-

tion with other acne medications, were described. Details of these case reports are summarized in **Table 2**. In case reports 1 and 2, monotherapy with the topical clindamycin 1%/benzoyl peroxide 5% gel achieved marked reductions in the number of inflammatory papules, pustules, and nodules in both patients. In case report 3, daily use of the topical clindamycin 1%/benzoyl peroxide 5% gel yielded dramatic improvement of facial inflammatory papules and pustules after 4 weeks of treatment. The

combination of the clindamycin 1%/benzoyl peroxide 5% and adapalene gels produced marked clinical improvement in case reports 4 and 5, whereas the combination of topical clindamycin 1%/benzoyl peroxide 5% gel, adapalene, and oral doxycycline was especially effective in case report 6.

Overall, the patient experience described demonstrates the efficacy and tolerability of topical clindamycin 1%/benzoyl peroxide 5% gel, both as monotherapy and in combi-

nation with other agents used for acne vulgaris. The complementary mechanisms of action of topical clindamycin 1%/benzoyl peroxide 5% gel, adapalene, and doxycycline may contribute to the increased efficacy and faster onset of action achieved with these combinations.

Based on: Bikowski JB. Case study results of Duac® (clindamycin 1%/benzoyl peroxide 5%) gel as monotherapy and in combination. Poster presented at: 63rd Annual Meeting of the American Academy of Dermatology; February 18-22, 2005; New Orleans, La. Abstract P118. ■

Table 2. Case Reports of Successful Use of Clindamycin/Benzoyl Peroxide Gel as Monotherapy and in Combination for Acne Vulgaris

Case	Patient	Previous Therapy	Current Therapy	Outcome of Current Therapy
1	26-year-old female with ≥10-year history of acne vulgaris	Non-Rx products	Clindamycin/benzoyl peroxide gel qAM on entire face; non-Rx cleanser	75%-80% improvement after 6 weeks of treatment
2	18-year-old male with a 2-month flare-up of moderately severe acne	Non-Rx benzoyl peroxide/sulfur product for 2 months; adapalene gel x 4 days	Clindamycin/benzoyl peroxide qHS; non-Rx cleanser BID	70% improvement after 6 weeks of treatment
3	18-year-old male with inflammatory papules and pustules	Ketoconazole PO; adapalene gel	Clindamycin/benzoyl peroxide gel qHS on face, neck, shoulders, and back; ciclopirox 1% shampoo on scalp, face, shoulders, and back	Dramatic improvement in facial lesions after 4 weeks of treatment; ciclopirox 1% shampoo added
4	17-year-old male with inflammatory papules and comedones	Adapalene gel qHS; non-Rx cleanser BID	Clindamycin/benzoyl peroxide gel qAM; adapalene gel qHS; non-Rx cleanser BID	Marked decrease in inflammatory lesions on forehead, nose, cheeks, and chin after 4 weeks of therapy; decrease in new lesions after 6 more weeks of therapy
5	23-year-old female with acne vulgaris	Benzoyl peroxide 6% BID; adapalene gel qHS; non-Rx moisturizer; non-Rx cleanser	Clindamycin/benzoyl peroxide gel qAM on entire face; adapalene gel qHS	Decrease in new lesions and marked improvement on chin after 6 weeks
6	17-year-old male with acne vulgaris	Tretinoin qHS; doxycycline 100 mg QD; adapalene gel qHS; non-Rx cleanser BID	Clindamycin/benzoyl peroxide gel qAM; doxycycline 100 mg QD; adapalene gel qHS	Marked decrease in all new lesions with minimal postinflammatory erythema after 6 weeks

BID = twice daily; Non-Rx = nonprescription; PO = by mouth; qAM = every morning; qHS = at bedtime; QD = daily.

Patient Preference for Clindamycin/Benzoyl Peroxide Gel Formulations

Factors other than active ingredients may have significant impact on the safety and efficacy of topical acne products. Important factors in these products include excipients and packaging, which can affect patient preference and in turn compliance. To examine the factors that influence patient preference in selecting topical acne medications, a two-center crossover study was conducted in 52 patients with mild to moderate acne vulgaris of the face.

Patients were randomized to receive two gel formulations of clindamycin/benzoyl peroxide. Although the two products contained the same active ingredients, they contained different excipients, were packaged differently, and had different dosing schedules. One of the products contained dimethicone and glycerin,

was available in a ready-to-dispense tube, and was used once daily. The other product was available in a jar, required mixing at the pharmacy before dispensing, and was intended for twice-daily use.

Patients received each product in a crossover design for 2 weeks, with treatment periods separated by a 2-week washout period in which they were instructed to use a non-prescription cleanser. Subjects were instructed to apply the tube gel once daily (before bedtime) and the jar gel twice daily (in the morning and before bedtime). Use of topical moisturizers on the face was prohibited during the study.

Overall, the number of inflammatory and noninflammatory lesions decreased with both treatments, and the subjects did not perceive a difference in efficacy between the two products. However, 73%

of the subjects thought that the tube gel had fewer adverse effects than did the jar gel ($P < 0.05$). More subjects reported dryness on local tolerance scores with the jar gel than with the tube gel ($P < 0.05$) (Figure 4). Based on the investigator's clinical scores, more subjects experienced peeling with the use of the jar gel than with the tube gel ($P < 0.05$) (Figure 5), although incidence of erythema, pruritus, and burning did not differ between the two products.

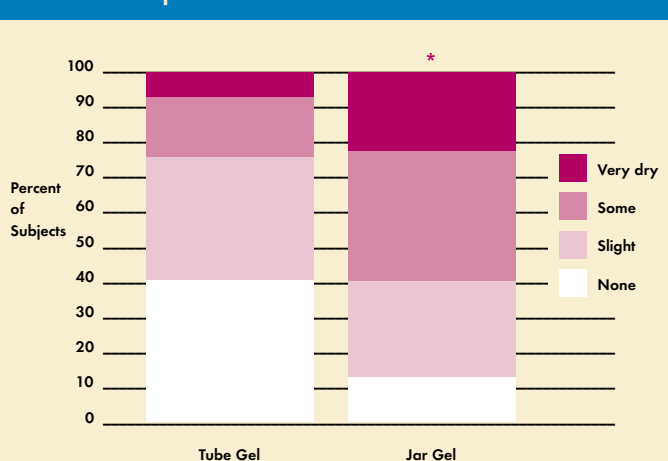
According to a patient questionnaire, 76% of the subjects preferred the tube gel to the jar gel ($P < 0.05$). Specifically, significantly more subjects found that the tube gel was easier and less messy to use, easier to carry, and less likely to become contaminated, and took less room to store than was the jar gel; moreover, it was easier to dispense the

right amount of medication with the tube gel ($P < 0.05$). Additionally, 77% of subjects preferred once-daily use of medication as compared to 23% who preferred twice-daily use ($P < 0.05$).

The results of this study suggest that patient preference for topical acne medications is impacted substantially by the product packaging and dosage regimen. Further, the inclusion of emollients in topical acne medications may lead to better tolerability and greater patient preference.

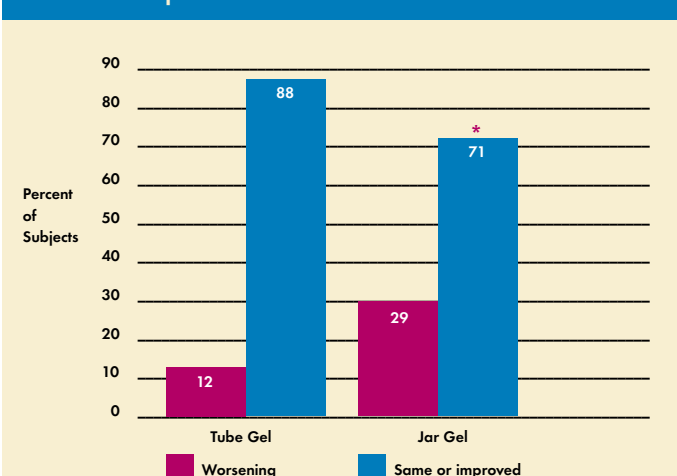
Based on: Tanghetti EA, Gold MH, Fraser JM. A two-center patient preference study comparing two benzoyl peroxide/clindamycin gels in acne vulgaris patients. Poster presented at: 63rd Annual Meeting of the American Academy of Dermatology; February 18-22, 2005; New Orleans, La. Abstract P108. ■

Figure 4. Comparison of Local Tolerability of Clindamycin/Benzoyl Peroxide Gel Dispensed in a Tube vs in a Jar



Subjects' local tolerance scores for dryness after 2 weeks of treatment with tube gel or jar gel (periods 1 and 2 combined). * $P < 0.05$.

Figure 5. Comparison of Peeling Occurring With Clindamycin/Benzoyl Peroxide Gel Dispensed in a Tube vs in a Jar



Change in investigator's clinical scores for peeling after 2 weeks of treatment with tube gel or jar gel (periods 1 and 2 combined). * $P < 0.05$.

Quantitative Assessment of the Application and Consumption of Topical Acne Medication by Patients

Proper application and compliance are important components of successful acne management. Factors that may influence treatment outcome include prescribing the appropriate quantity of medication needed per application, the physical characteristics of the formulation, and the method of application.

The quantity and method of application of topical medication to the face were evaluated in a three-part clinical trial. In the first phase of the trial, product distribution of four vehicles (water-based gel, thick-viscosity cream, cream in a tube, lotion in a bottle) was evaluated using skin fluorescent techniques in two volunteers without acne or any other facial dermatoses. Participants were instructed to apply two vehicles, with applications separated by 4 weeks. The method of application

used initial “dot” application of a fingertip unit to each of nine designated points. Each of the four test vehicles had been mixed with fluorescein to allow for ultraviolet light exposure to illuminate skin areas where vehicle was deposited [*Dermatol Surg.* 2004; 30:784-786]. After completion of each application, ultraviolet light exposure determined that the method of application used allowed for even distribution of all four vehicles to the forehead, cheeks, chin, and nose.

The second phase of the study evaluated the quantity of medication used after application to the skin using the same application method used in phase 1. Ten participants without acne or other facial skin disease applied cream, thick-viscosity cream, lotion, water-based gel from a tube, and water-based gel from a wide-mouthed jar once daily for 7

days. Each participant used all four vehicles consecutively in a randomized order, leading to a total study duration of 35 days. The pretreatment weight of each container was recorded

differed among the vehicles after single application and once-daily use for 7 days. The mean quantity after single use was 0.69 g, 0.78 g, 0.86 g, 0.69 g, and 0.80 g for the cream, thick cream, lotion, gel from a tube, and gel from a jar, respectively. Mean quantities used after extrapolating to 28 days were 19.96 g, 23.08 g, 25.56 g, 19.88 g, and 23.24 g for the cream, thick cream, lotion, gel from a tube, and gel from a jar, respectively (**Figures 6A and 6B**).

In phase 3 of the study, 20 patients with untreated acne vulgaris were prescribed a 2-g sample tube and a 45-g tube of clindamycin 1%/benzoyl peroxide 5% water-based gel for once-daily application. At the initial visit, patients applied the product using the sample tube without instructions for use under investiga-

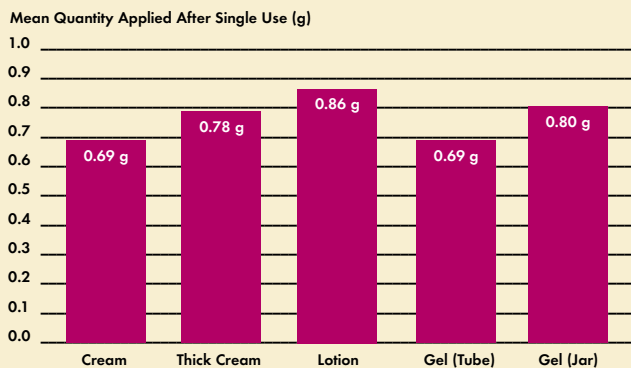
ed by the investigator at baseline, after the first application, and at the end of the 7-day usage period using a precision balance.

The quantity of each vehicle as determined by weight

Factors that may influence treatment outcome include prescribing the appropriate quantity of medication needed per application, the physical characteristics of the formulation, and the method of application.

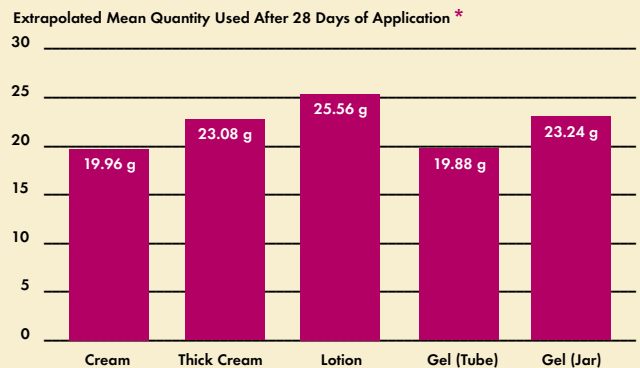
Continued on page 8

Figure 6A. Mean Quantities of Vehicle Applied Using Recommended Application Method (Once-Daily Use)



Mean quantities of vehicles applied using recommended application method (once-daily use).

Figure 6B. Estimated Mean Quantity Used After 28 Days of Application



Mean quantities of vehicles applied using recommended application method (once-daily use). *28 days extrapolated from 7-day data (mean from 10 participants x 4); does not correct for potential increment in product “waste” with repeated use which may increase total amount applied over time.

Sulfacetamide/Sulfur Combination With Sunscreens for Rosacea

Sulfacetamide 10%/sulfur 5% cream with sunscreens has been demonstrated to be a safe and effective monotherapy for rosacea [*Skin Aging*. 2003;Oct (suppl):17-22]. The addition of both an ultraviolet (UV)-A blocker (avobenzone) and UVB blocker (octinoxate) sun protective factor-18 to this formulation provides photoprotection, which is an integral component of the therapeutic program for rosacea. Although few controlled clinical trials have evaluated combination therapies for rosacea, observational experience suggests that topical sulfacetamide-sulfur is effective in combination with other topical agents.

Clinical experience with rosacea patients treated with sulfacetamide/sulfur cream with sunscreens combined with either topical metronidazole or azelaic acid once daily

was described. Patients were graded as having either moderate or severe rosacea based on the intensity of erythema and number of inflammatory lesions. Patients were divided into two treatment groups and were instructed to apply sulfacetamide/sulfur cream with sunscreens in the morning and either topical metronidazole 0.75% gel or azelaic acid 15% gel in the evening. Gentle facial cleanser and moisturizer preparations were provided for all patients, with instruction on proper use and application. Patients were followed up every 5 to 6 weeks for two follow-up appointments, with the final appointment ranging between 10 and 12 weeks after baseline.

According to investigator assessment of the 22 patients who received combination sulfacetamide/sulfur cream with sunscreens and metronidazole, overall severity in 20 patients

improved by at least 1 grade in severity assessment after 4 to 6 weeks. Marked reduction in erythema and telangiectasia intensity were also noted in several patients by study endpoint. Of the 14 patients who received sulfacetamide/sulfur cream with sunscreens in combination with azelaic acid, 13 patients experienced improvement in overall severity by 4 to 6 weeks, with erythema and telangiectasia index improving in most patients by the end of the study. Both combination regimens produced complete clearance of rosacea in a subset of patients. All regimens were well tolerated, with dryness, mild scaling or peeling, and mild transient erythema that resolved after the first week of therapy being the most frequently reported adverse events.

This observational experience indicates that sulfacetamide 10%/sulfur 5% cream

with sunscreens may be combined safely and effectively with once-daily use of either topical metronidazole or azelaic acid gel. Significant improvement was achieved with these regimens after 4 to 6 weeks of therapy in a substantial number of patients with further improvement observed in some patients with continued use. Controlled data are necessary to further evaluate and clarify the role of such combination regimens in patients with rosacea.

Based on: Del Rosso JQ. The impact of a combination formulation of sulfacetamide 10%-sulfur 5% with sunscreens cream on the management of rosacea. Poster presented at: 63rd Annual Meeting of the American Academy of Dermatology; February 18-22, 2005; New Orleans, La. Abstract P152. ■

Quantitative Assessment

Continued from page 7

tor observation. Patients were then instructed on the application method used in phase 2 and directed to use the 45-g tube for the following 30 days. All tubes were weighed with a precision balance prior to use, after the initial application, and at the end of the 30-day use period. Inflammatory lesion counts were recorded at baseline and at the final visit.

At the first product application, seven patients "spot" applied to lesions only, averaging 0.34 g (range, 0.2-0.4 g) in the application. The remaining

13 patients used a mean of 0.9 g (range, 0.6-1.2 g) in the single application. After patients received instruction on the method of application, a mean of 0.71 g (range, 0.5-0.8 g) was recorded for a single application. After 30 days, the mean quantity of drug used was 21.6 g and mean inflammatory lesion count was reduced from 13.5 at baseline to 5.1 (62.2% reduction).

These results underscore the importance of patient education with regard to method of topical application,

as well as the choice of a topical application method that allows for even product spread and distribution. Further, the quantity of drug used with topical application may be influenced significantly by the type of vehicle used, product characteristics such as viscosity, and type of packaging. Finally, understanding the quantity of drug used per application can allow clinicians to predict the duration and quantity that prescribed medication should last if applied appropriately. These data illus-

trate that when applied properly, a 45-g tube of clindamycin 1%/benzoyl peroxide 5% water-based gel should last approximately 2 months if used once daily as is recommended.

Based on: Del Rosso JQ. A qualitative and quantitative assessment of the application and consumption of topical acne medication by patients. Poster presented at: 63rd Annual Meeting of the American Academy of Dermatology; February 18-22, 2005; New Orleans, La. Abstract P106. ■