

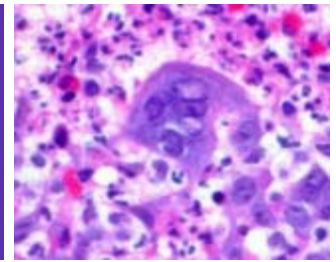


eLITERATURE REVIEW

eMedicalDermatology Review

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Acne Update

In this Issue...

Acne vulgaris is the most common facial dermatologic disorder encountered in clinical practice. Although the condition affects mainly teenagers, many individuals experience acne onset early in their preteen years or in later adulthood. Despite the common nature of acne vulgaris, effective control of the condition remains a formidable challenge primarily because of the chronicity of the disorder. Management of acne vulgaris involves several important factors, including grading of disease severity, appropriate selection of medications, consideration of potential adverse effects of therapy, development of a convenient treatment regimen, and enhancement of patient compliance.

Most patients with mild to moderate acne vulgaris require treatment with a combination of topical agents and, in some cases, an oral antibiotic. Treatment outcomes are maximized by using a combination approach that is convenient, well tolerated, and includes different mechanisms of action. In this issue, we discuss antibiotic use in patients with acne vulgaris, topical retinoids as part of combination therapy, the incidence of acne flaring following initiation of topical retinoid therapy, and the use of oral contraceptives in female patients with acne vulgaris.



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[CE Info](#)
[Accreditation](#)
[Credit Designations](#)
[Intended Audience](#)
[Learning Objectives](#)
[Internet CME/CNE Policy](#)
[Faculty Disclosure](#)
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THIS ISSUE

- [COMMENTARY from our Guest Authors](#)
- [CLINICAL CONSIDERATIONS WITH ANTIBIOTIC USE FOR THE TREATMENT OF ACNE VULGARIS](#)
- [TOPICAL RETINOID THERAPY FOR THE MANAGEMENT OF ACNE VULGARIS](#)
- [POTENTIAL FOR ACNE FLARING FOLLOWING INITIATION OF TOPICAL RETINOID THERAPY](#)
- [USE OF ORAL CONTRACEPTIVES FOR THE TREATMENT OF ACNE VULGARIS IN WOMEN](#)

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Guest Faculty Disclosures

Dr. Del Rosso has served as a consultant, speaker and investigator for Allergan, Coria, Galderma, Intendis, Medicis, Ortho Neutrogena, Onset, QLT, Quinnova, Ranbaxy, SkinMedica, Stiefel, Triax, Unilever and Warner Chilcott.

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LEARNING OBJECTIVES

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

- Explain the rationale behind combination therapy for the management of acne vulgaris
- Outline clinical considerations regarding *Propionibacterium acnes* resistance in the treatment of acne vulgaris
- Describe a management plan for individuals with acne vulgaris based on clinical presentation and patient-specific factors

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[back to top](#)

COMMENTARY

Acne vulgaris is one of the most common disorders encountered in clinical practice, accounting for almost 12% of annual visits to dermatologists in the United States. Management remains challenging because of the chronic nature of the disorder. Compliance with treatment is integral to the success of therapy. Additionally, a visibly acceptable response to therapy may take 2 to 3 months or longer, leading to patient frustration. However, studies demonstrate that effective therapy is achievable if patients adhere to their treatment regimen.

Currently, the most commonly used topical agents for the treatment of acne vulgaris include benzoyl peroxide, antibiotics (clindamycin in particular), and retinoids. The articles by Del Rosso and colleagues (2008), Campbell (2007), and Del Rosso (2007) address the optimal use of topical agents, especially as combination therapy. Over time, chronic antibiotic use in patients with acne vulgaris has resulted in a worldwide increase in the prevalence of antibiotic-resistant *Propionibacterium acnes* strains. As such, the use of benzoyl peroxide in combination with a topical antibiotic has been shown to reduce the emergence and proliferation of antibiotic-resistant strains of *P. acnes*. When an oral antibiotic is prescribed or when truncal acne is present, a benzoyl peroxide wash is recommended for more widespread application, such as to the trunk and upper arms. In their articles, Campbell and Del Rosso discuss optimal use of topical retinoids in combination with other agents. It has become apparent when prescribing a benzoyl peroxide-containing product (such as benzoyl peroxide/clindamycin gel) along with a topical retinoid that the most rapid, greatest reduction in acne lesions occurs when both agents are applied once daily from the outset. It is generally recommended that the benzoyl peroxide-containing product be applied in the morning and the topical retinoid in the evening.

Another combination topical agent that has been beneficial in the management of acne vulgaris is clindamycin phosphate 1.2% plus tretinoin 0.025% gel. Pivotal 12-week trials demonstrate greater efficacy with the combination product than with the individual active component or vehicle.¹ Efficacy was demonstrated over the 12-week duration of the studies without the concomitant use of benzoyl peroxide. The article by Leyden and Wortzman evaluates the association of acne flaring with topical retinoid therapy, based on more than 4000 subjects included in 3 separate phase III studies of clindamycin/ tretinoin combination gel. The incidence of acne flaring, defined as a $\geq 20\%$ increase in inflammatory lesions after 2 weeks, was shown to be $< 15\%$ in subjects treated with topical tretinoin monotherapy and correlated somewhat inversely with acne severity. The presence of clindamycin demonstrated the potential to blunt acne flaring.

Oral contraceptive therapy may be helpful in females with acne vulgaris. An oral contraceptive containing drospirenone 3mg and ethinyl estradiol 20 μg has been approved by the US Food and Drug Administration for the treatment of acne vulgaris. The

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significance of drospirenone is the fact that the agent exhibits antiandrogenic activity. The study by Lucky and associates demonstrated that treatment with this oral contraceptive produced a progressive decrease in superficial inflammatory and noninflammatory acne lesions over 6 treatment cycles. Importantly, a reasonably noticeable reduction in acne lesions is not likely to occur for at least 3 treatment cycles and sometimes longer.

The information described above reflects my most commonly used therapies for the management of acne vulgaris. With respect to oral contraceptive use in females with post-teenage acne, the concomitant use of oral spironolactone is often beneficial.² When such a combination is used, the oral contraceptive serves to reduce the menstrual irregularities and breast tenderness that may be associated with the use of oral spironolactone, especially at doses >100 mg per day.

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1. Schlessinger J, Menter A, Gold M, et al; ZIANA Study Group. [Clinical safety and efficacy studies of a novel formulation combining 1.2% clindamycin phosphate and 0.025% tretinoin for the treatment of acne vulgaris](#). *J Drugs Dermatol*. 2007;6(6):607-615.
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[back to top](#)

CLINICAL CONSIDERATIONS WITH ANTIBIOTIC USE FOR THE TREATMENT OF ACNE VULGARIS

Del Rosso JQ, Leyden JJ, Thiboutot D, Webster GF. **Antibiotic use in acne vulgaris and rosacea: clinical considerations and resistance issues of significance to dermatologists**. *Cutis*. 2008;82(suppl 2[iii]):5-12.

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This article provides an update from The Scientific Panel on Antibiotic Use in Dermatology, with a major focus on clinical considerations when using topical and oral antibiotics for the treatment of acne vulgaris. The role of antibiotics in acne vulgaris relates primarily to the reduction in *Propionibacterium acnes*, resulting predominantly in a decrease in inflammatory lesions. Over time, changes in the sensitivity of *P. acnes* to antibiotics has necessitated modifications in treatment recommendations.

Topical and oral antibiotics, which are widely prescribed by dermatologists across the United States for the treatment of acne vulgaris, account for 11 to 12 million annual prescriptions. Over the past 3 to 4 decades, a marked increase in *P. acnes* resistance to commonly used antibiotics, such as erythromycin and tetracycline, has been observed worldwide. Although it exists to some degree, *P. acnes* resistance is less prevalent with doxycycline and the least prevalent with minocycline. Decreased sensitivity of *P. acnes* to antibiotics has been associated with a reduced therapeutic response in some patients with acne.

On the other hand, despite the increase in *P. acnes* antibiotic resistance, many topical and oral antibiotics that have been used over the last 3 to 4 decades have continued to demonstrate efficacy in the treatment of acne vulgaris. This may be related to the anti-inflammatory properties of certain antibiotics, such as tetracyclines; to differences in follicular concentrations among agents; and to variations in mechanisms of antibiotic resistance, even among antibiotics from the same chemical class. For example, despite the common finding of cross-resistance between erythromycin and clindamycin, an assessment of clinical trials has confirmed that over time, topical clindamycin has noticeably sustained its efficacy in reducing acne lesions compared with topical erythromycin.¹ Similar findings have been reported with oral doxycycline and minocycline.²

Another concern regarding prolonged antibiotic use for such chronic disorders as acne vulgaris, especially with oral agents, is selection pressure and its effects on flora other than *P. acnes*. Increased colonization of the oropharynx with *Streptococcus pyogenes*,

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including an increase in tetracycline-resistant strains, has been observed in antibiotic-treated acne patients vs those not receiving antibiotic therapy.³ Epidemiologic data have suggested an approximate 2-fold greater risk for upper respiratory tract infections in acne patients treated with antibiotics compared with those who are not.⁴ Currently, no definitive evidence suggests that antibiotic therapy for acne has resulted in clinically significant sequelae related to antibiotic selection pressure.

It is recommended that antibiotic monotherapy not be used for the treatment of acne vulgaris, especially over a prolonged period of time. Additionally, since benzoyl peroxide has been shown to reduce the emergence and proliferation of antibiotic-resistant *P. acnes* strains, use of this agent is recommended in patients treated with antibiotics for acne vulgaris. Leave-on formulations of benzoyl peroxide are associated with the greatest reduction in *P. acnes* counts; however, a benzoyl peroxide 6% cleanser has been shown to markedly reduce antibiotic-resistant *P. acnes* strains. This latter observation is highly applicable for treatment of the truncal region, especially when the patient is on an oral antibiotic. Topical retinoids are an important component of acne management, are not associated with antibiotic resistance, and are effective as part of long-term maintenance in controlling acne lesions.

This article discusses several important clinical considerations regarding antibiotic use in acne management. Clinicians should be mindful of the overall ecological effects of antibiotic use, both topical and oral. When prescribed, antibiotics are best used as part of a combination therapy approach, with the inclusion of benzoyl peroxide to reduce the emergence of *P. acnes* resistance. When clinically feasible, the duration of oral antibiotic therapy is best limited to what is needed to achieve control of disease, with continuation of a combination topical approach to sustain long-term maintenance.

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1. Simonart T, Dramaix M. [Treatment of acne with topical antibiotics: lessons from clinical studies](#). *Br J Dermatol*. 2005;153(2):395-403.
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[back to top](#)

TOPICAL RETINOID THERAPY FOR THE MANAGEMENT OF ACNE VULGARIS

Campbell JL Jr. **A comparative review of the efficacy and tolerability of retinoid-containing combination regimens for the treatment of acne vulgaris.** *J Drugs Dermatol*. 2007;6(6):625-629.

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Del Rosso JQ. **Study results of benzoyl peroxide 5%/clindamycin 1% topical gel, adapalene 0.1% gel, and use in combination for acne vulgaris.** *J Drugs Dermatol*. 2007;6(6):616-622.

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These 2 articles discuss the use of topical retinoids as an important component of topical combination therapy for acne vulgaris. Although topical retinoids may be used as monotherapy for mild, predominantly non-inflammatory (comedonal) acne, they are frequently used in combination with other agents, such as benzoyl peroxide and antibiotics, to maximize therapeutic benefits. It has been demonstrated that the most rapid,

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effective approach is achieved when a topical retinoid is used at the outset of treatment, along with other prescribed agents.

Topical retinoids have been shown to reduce both inflammatory and non-inflammatory acne lesions through a variety of cellular mechanisms. Importantly, topical retinoids exhibit the ability to reduce follicular hyperkeratosis and display direct anti-inflammatory effects, including a reduction in the innate immune response triggered by *P. acnes* (downregulation of toll-like receptor 2). Three different retinoids are currently available in a variety of topical formulations: tretinoin, adapalene, and tazarotene. Campbell discusses the use of topical retinoids in combination with other agents, such as benzoyl peroxide and antibiotics, based on results from multiple studies. All of the topical retinoids are effective, both as monotherapy and in combination with other agents. Differences among the topical retinoids have been reported relative to tolerability, stability in the presence of ultraviolet light, and chemical compatibility with benzoyl peroxide. Adapalene is stable in the presence of ultraviolet light and in the presence of benzoyl peroxide. Other than in the microsphere formulation, tretinoin is photolabile and unstable when applied concurrently with benzoyl peroxide.

Tolerability is an important issue with topical retinoid use, especially with combination therapy, as individual components of the each regimen have their own tolerability profiles. With respect to cutaneous tolerability, adapalene in both gel and cream formulations exhibits a favorable tolerability profile. The microsphere and aqueous gel formulations of tretinoin have improved tolerability of the agent compared with conventional formulations. Tazarotene cream is more tolerable than the gel formulation.

Del Rosso demonstrates that combined use of a benzoyl peroxide 5% plus clindamycin 1% gel applied in the morning and a topical retinoid applied at night is associated with the greatest reduction in acne lesions (inflammatory, non-inflammatory, total) over the first 12 weeks of therapy (study duration), compared with alternating initiation of the topical agents. In this study, adapalene gel 0.1% was the topical retinoid used. Other studies have confirmed similar findings, demonstrating the optimal efficacy of combination therapy with a benzoyl peroxide/clindamycin gel applied in the morning and a topical retinoid in the evening.^{1,2}

Importantly, the formulation of benzoyl peroxide/clindamycin used in combination trials with a topical retinoid was the tube gel vehicle, which contains a humectant (glycerin) and an occlusive emollient (dimethicone). The tolerability of this combination formulation proved to be very favorable when used along with topical retinoid therapy. The vehicle formulations of the various products may affect cutaneous tolerability, especially when used in a combination regimen.

Topical retinoids are well recognized as a pivotal component of topical acne management because of their different modes of action, their ability to prevent microcomedo formation, their potential for reducing both inflammatory and non-inflammatory lesions, and their value in long-term maintenance therapy. Since topical retinoids are not associated with the potential for antibiotic resistance, they are well suited for both short-term and long-term use. Both of the articles discussed herein present data that support the therapeutic benefits of topical retinoids used in combination with other agents, such as benzoyl peroxide and antibiotics. Lesion count reductions are augmented with the inclusion of a topical retinoid as part of the treatment regimen.

A factor that may have limited the use of topical retinoids as a component of the initial topical regimen is skin tolerability, as an initial phase of “retinoid dermatitis” is common in the first 2 to 4 weeks of use. Newer retinoid compounds and/or vehicle formulations have reduced this concern. Additionally, the availability of benzoyl peroxide in a vehicle formulation that improves skin tolerability without the loss of efficacy has further improved the tolerability of topical combination regimens.

An important take-home message from these 2 reviews is that optimal reduction in acne lesions is achieved when therapies are combined from the outset, including topical retinoids. Issues related to skin tolerability may be reduced by selecting formulations known to be less irritating and by promoting proper skin care, including moisturization.

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2. Kircik L. [Community-based trial results of combination clindamycin 1%–benzoyl peroxide 5% topical gel plus tretinoin microsphere gel 0.04% or 0.1% or adapalene gel 0.1% in the treatment of moderate to severe acne](#). *Cutis*. 2007;80 (1 suppl):10-14.

[back to top](#)

POTENTIAL FOR ACNE FLARING FOLLOWING INITIATION OF TOPICAL RETINOID THERAPY

Leyden JJ, Wortzman M. **A novel gel formulation of clindamycin phosphate-tretinoin is not associated with acne flaring**. *Cutis*. 2008;82(2):151-156.

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Initial flaring of acne has been associated with initiation of therapy with a topical retinoid. Although this possibility has been noted based on anecdotal observation, until recently, a controlled study evaluating acne flaring after initiation of retinoid therapy had never been completed. In 3 multicenter, randomized, double-blind, phase 3 trials of subjects with acne vulgaris of all severities, the efficacy and safety of a clindamycin phosphate 1.2% plus tretinoin 0.025% combination gel was compared with the individual active agents and vehicle in a total of 4550 subjects. One of the assessment parameters included in these studies was the incidence of acne flaring observed within the first 2 weeks following initiation of therapy.

In the current study, acne flaring was assessed after 2 weeks of therapy in all treatment arms from the 3 studies. Flaring of acne was evaluated at week 2 using 2 separate measures: 1) a $\geq 10\%$ increase in inflammatory lesions, and 2) a $\geq 20\%$ increase in inflammatory lesions. If a topical retinoid (in this study, tretinoin was used) was associated with acne flaring, one would expect to see a greater number of inflammatory lesions at week 2 in the tretinoin-treated group than in subjects treated with vehicle. The incidence of acne flaring, defined as a $\geq 10\%$ increase in inflammatory lesions, in subjects treated with tretinoin gel 0.025% alone (n=846) was 15.4% in both those with mild and those with moderate acne, and 12.7% in those with severe acne, compared with 8.7%, 17.5%, and 23.8%, respectively, in those treated with vehicle. The incidence of acne flaring, defined as a $\geq 20\%$ increase in inflammatory lesions, in subjects treated with tretinoin gel 0.025% alone (n=846) was 9.9% in those with mild acne, 10.2% in those with moderate acne, and 8.5% in those with severe acne, vs 6.5%, 12.1%, and 12.7%, respectively, in those treated with vehicle. The clindamycin monotherapy arm (n=1428) and the clindamycin/tretinoin combination gel arm (n=1853) were associated with comparable rates of acne flaring using both definitions, which were considerably lower than the incidence of acne flaring in tretinoin gel-treated subjects, especially those with acne of mild or moderate severity.



Pivotal studies have shown the combination aqueous gel containing clindamycin phosphate 1.2% plus tretinoin 0.025% to be effective and well tolerated.¹ An important assessment conducted during the phase III studies with this agent was of acne flaring associated with the initiation of topical retinoid therapy. Interestingly, acne flaring had not been evaluated as an individual assessment parameter in previous acne studies. The results from this trial indicate that acne flaring following initiation of topical retinoid use (ie, tretinoin) is relatively uncommon and correlates somewhat inversely with the baseline severity of acne vulgaris. Based on this study, the use of topical clindamycin appeared to blunt the potential for acne flaring when combined with topical tretinoin.

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1. Schlessinger J, Menter A, Gold M, et al; ZIANA Study Group. [Clinical safety and efficacy studies of a novel formulation combining 1.2% clindamycin phosphate and 0.025% tretinoin for the treatment of acne vulgaris](#). *J Drugs Dermatol*. 2007;6(6):607-615.

[back to top](#)

USE OF ORAL CONTRACEPTIVES FOR THE TREATMENT OF ACNE VULGARIS IN WOMEN

Lucky AW, Koltun W, Thiboutot D, et al. **A combined oral contraceptive containing 3-mg drospirenone/20-µg ethinyl estradiol in the treatment of acne vulgaris: a randomized, double-blind, placebo-controlled study evaluating lesion counts and participant self-assessment**. *Cutis*. 2008;82(2): 143-150.

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The use of oral contraceptives for the management of acne vulgaris is well recognized, particularly in women with post-adolescent acne lesions. A combined oral contraceptive containing drospirenone 3 mg and ethinyl estradiol 20 µg has been approved by the US Food and Drug Administration for the treatment of moderate acne vulgaris in female patients. This double-blind, randomized trial compared the efficacy and safety of this oral contraceptive agent (n=191) with placebo (n=188) over 6 treatment cycles. The time course of the response was evaluated, and the effects on serum levels of sex hormone-binding globulin, free testosterone, total testosterone, and androstenedione were measured.

The combined oral contraceptive tablet containing drospirenone 3 mg plus ethinyl estradiol 20 µg is administered daily for 24 days, with 4 days of inert tablets also given (24/4 regimen). In this study, those treated with the active oral contraceptive agent achieved a statistically significant mean change from baseline in papules ($P=.0002$), pustules ($P=.0119$), and closed comedones ($P=.0002$). The separation between the active treatment and the placebo groups with respect to reduction in inflammatory and non-inflammatory lesions was noted from the third treatment cycle through the end of the study, with a progressive reduction in lesion counts observed over the duration of the trial. Compared with placebo, treatment with the oral contraceptive agent was associated with significantly decreased serum levels of free testosterone ($P=.0004$) and androstenedione ($P=.0298$), and significantly increased serum levels of sex hormone-binding globulin ($P=.0021$). The serum levels of total testosterone and dehydroepiandrosterone sulfate were essentially unchanged.

The efficacy of oral contraceptives for the management of acne vulgaris has been confirmed in this trial and in others.^{1,2} Reduction in both superficial inflammatory lesions (papules, pustules) and noninflammatory lesions occurs progressively over time. Importantly, in this study, the onset of significant clinical efficacy was reported from the third treatment cycle, emphasizing the significance of informing patients that a meaningful clinical response does not usually take place for at least 3 months. Overall, treatment was well tolerated in both the active and placebo groups.

The combined oral contraceptive tablet containing drospirenone 3 mg plus ethinyl estradiol 20 µg appears to be efficacious in controlling acne, due primarily to its antiandrogenic activity. The increase in serum levels of sex hormone-binding globulin, and the decrease in serum levels of free testosterone and androstenedione, all help to reduce androgenic

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stimuli, which can exacerbate acne vulgaris. In addition, drospirenone 3 mg is equivalent in antiandrogenic activity to a spironolactone dose of approximately 25 mg. Lastly, the 24/4 regimen allows for a shortening of the duration of menses, which may potential blunt perimenstrual acne flares. Clinicians should become familiar with potential cautions and contraindications associated with prescribing oral contraceptives prior to initiating their use.

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[back to top](#)

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

- Explain the rationale behind combination therapy for the management of acne vulgaris
- Outline clinical considerations regarding *Propionibacterium acnes* resistance in the treatment of acne vulgaris
- Describe a management plan for individuals with acne vulgaris based on clinical presentation and patient-specific factors

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