
Two randomized studies demonstrate the efficacy and safety of dapsone gel, 5% for the treatment of acne vulgaris

Zoe D. Draelos, MD,^a Eric Carter, MD,^b J. Michael Maloney, MD,^c Boni Elewski, MD,^d Yves Poulin, MD,^e Charles Lynde, MD,^f and Steven Garrett, DDS,^g for the United States/Canada Dapsone Gel Study Group*
High Point, North Carolina; New York, New York; Denver and Fort Collins, Colorado; Birmingham, Alabama; Sainte-Foy, Quebec, and Markham, Ontario, Canada

Background: A new aqueous gel formulation of dapsone has been developed that allows clinically-effective doses of dapsone to be administered topically with minimal systemic absorption.

Objectives: The goal of these studies was to evaluate the efficacy and safety of dapsone gel, 5% in the treatment of acne.

Methods: Patients 12 years of age and older with acne vulgaris (N = 3010) participated in two identically-designed 12-week, randomized, double-blind studies of twice-daily monotherapy with dapsone gel, 5%, versus a vehicle gel.

Results: Dapsone gel-treated patients achieved superior results in terms of the investigator's global acne assessment ($P < .001$) and the mean percentage reduction in inflammatory, noninflammatory, and total lesion counts (all, $P < .001$) at week 12. Reductions in inflammatory lesion counts favoring dapsone gel over vehicle were apparent as early as 2 weeks and reached statistical significance by 4 weeks. No clinically significant changes in laboratory parameters, including hemoglobin, even among glucose-6-phosphate dehydrogenase-deficient patients, were observed. Adverse events were comparable between the treatment groups and rarely led to discontinuation.

Limitations: Adjunctive topical treatments and their impact on acne were not studied in this trial.

Conclusions: Dapsone gel, 5% appears to be an effective, safe, and well-tolerated treatment for acne vulgaris, with a rapid onset of action. (J Am Acad Dermatol 2007;56:439.e1-10.)

Acne is experienced almost universally by adolescents and young adults in westernized societies,¹⁻³ and in the United States it is one of the most common complaints for which individuals consult dermatologists.⁴ For many patients, acne poses a heavy psychosocial burden, negatively impacting mood, self-esteem, body image, and

perceived levels of social isolation.^{5,6} Successful treatment of acne significantly reduces symptoms of anxiety and depression and improves acne patients' quality of life.^{7,8}

Dapsone, a sulfone that has both anti-inflammatory and antimicrobial properties, was shown to be an effective treatment for acne, including inflammatory

From Dermatology Consulting Services, High Point^a; the Department of Dermatology, Columbia University Medical Center, New York^b; Cherry Creek Research, Inc, Denver^c; the Department of Dermatology, University of Alabama, Birmingham^d; Centre of Dermatology Research, Sainte-Foy^e; Lynde Center for Dermatology, Markham^f; and QLT USA, Inc, Fort Collins.^g

*Additional members of the United States/Canada Dapsone Gel Study Group are available at www.eblue.org as an online-only appendix to this article.

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Reprint requests: Zoe D. Draelos, MD, Dermatology Consulting Services, 2444 N Main St, High Point, NC 27262. E-mail: zdraelos@northstate.net.

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Abbreviations used:

GAAS: Global Acne Assessment Score
G6PD: glucose-6-phosphate dehydrogenase
ITT: intent-to-treat

nodulocystic acne, in the era predating the availability of isotretinoin.^{9,10} However, the use of oral dapsone for acne was never widespread because of its potential to cause systemic toxicity, and, until recently, efforts to develop a topical formulation of dapsone were hindered by the poor solubility of dapsone in the aqueous vehicles that are typically used in dermatologic products.

Advances in cutaneous pharmacology have produced an aqueous gel that allows clinically-effective doses of dapsone to be administered topically with minimal systemic absorption. The efficacy and safety of a new formulation, dapsone gel, 5% (Aczone; QLT USA, Inc. Fort Collins, Colo), in the treatment of acne vulgaris have been studied in two identically designed, pivotal trials.

METHODS**Study design**

Two 12-week, double-blind, randomized, parallel group, phase III studies were conducted under identical protocols to evaluate the efficacy and safety of dapsone gel, 5% (dapsone gel), compared with a vehicle gel control in the treatment of acne vulgaris. A total of 103 centers in the United States and Canada participated in the studies between November 2002 and September 2003.

Eligible patients were randomly assigned in a 1:1 ratio to either dapsone gel or vehicle gel according to a fixed-block computer-generated randomization table. The investigators, patients, and sponsor personnel were blinded to the treatment assignment, and patients were instructed not to bring their medications to the examination room or discuss the appearance of their study medication with the investigator. These procedures were established because the active and vehicle test articles were of a slightly different color. To maintain blinding, personnel who were not involved in efficacy or safety assessments conducted the drug accountability and test article weight assessments.

Patients were instructed to apply a thin layer of dapsone gel or vehicle gel twice daily to acne-involved areas of the face. Patients could also treat acne-affected areas other than the face; however, these areas were not assessed for efficacy. After washing with a standard noncomedogenic soap-free cleanser (Cetaphil; Galderma Laboratories, LP),

study drug was applied once in the morning and again at least 1 hour before bedtime to the entire affected area and rubbed in until it completely disappeared.

These studies were conducted in accordance with the ethical principles of the Declaration of Helsinki and in compliance with the Good Clinical Practice Guidelines. The protocols for each study center were reviewed and approved by an institutional review board or ethics committee. Written informed assent and consent was obtained from each patient or his/her parent or guardian, as appropriate, before the start of study procedures.

Patients

Male and female patients 12 years of age or older with a clinical diagnosis of acne vulgaris involving the face were enrolled in these studies. Patients were to have 20 to 50 inflammatory lesions (defined to include papules and pustules) and 20 to 100 noninflammatory lesions (comedones) above the mandibular line at baseline. Individuals with severe cystic acne, acne conglobata, or any active or developing nodules above the mandibular line at baseline were excluded from participation. Other exclusion criteria included concurrent use of topical drugs or treatments that could affect acne, including antibiotics and anti-inflammatory agents; use within 4 weeks before baseline of systemic immunosuppressive drugs or systemic medications or therapy known to affect acne or inflammatory responses; use of isotretinoin within 3 months of baseline; or known allergy or hypersensitivity to dapsone, sulfa drugs, or excipients of the dapsone gel product. Women of childbearing potential could not be pregnant or nursing, had to be practicing an effective method of birth control as determined by the enrolling physician, and, if using hormonal contraception, had to have been using a stable dose for a minimum of 3 months. Systemic contraceptives were not to be initiated during the study.

Efficacy and safety assessments

All patients underwent a dermatologic examination at screening/baseline and at weeks 2, 4, 6, 8, and 12. At each of these visits, investigators recorded a Global Acne Assessment Score (GAAS) (Table I) and counted the number of inflammatory and noninflammatory acne lesions present. The total lesion count was the sum of both inflammatory and noninflammatory lesions.

The primary efficacy end points were the proportion of patients achieving success based on the GAAS and the mean percent reduction from baseline in acne lesion counts at week 12. Success for GAAS

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