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Assessing efficacy of a fixed combination of clindamycin phosphate (1.2%) and low concentration benzoyl peroxide (2.5%) aqueous gel in the treatment of severe acne

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Background: Oral antibiotics or oral retinoids are often used as primary treatment in the management of severe acne and topical medications secondarily. However, there are additional side effect concerns with the use of systemic treatments.

Objective: To evaluate the reduction in inflammatory and noninflammatory lesions and treatment success achieved with a topical combination of clindamycin phosphate and low concentration benzoyl peroxide (clindamycin-BPO 2.5%) in subjects with severe acne and those with moderate acne.

Methods: Two thousand two hundred eighty-two subjects with moderate acne and 531 subjects with severe acne were enrolled in two multicenter double-blind studies and randomized 2:2:2:1 to receive a combination of clindamycin phosphate (1.2%) and low concentration benzoyl peroxide (2.5%), each active ingredient or vehicle, once daily for 12 weeks. Efficacy evaluations comprised inflammatory, noninflammatory, and total lesion counts and an evaluator global severity score (EGSS) on a scale from 0 (clear) to 5 (very severe) at baseline and weeks 4, 8, and 12.

Results: At week 12, absolute reductions in inflammatory lesion counts with clindamycin-BPO 2.5% from baseline were 14.7 and 14.1 in the severe and moderate acne treatment groups, respectively; absolute reductions in noninflammatory lesion counts were 23.6 and 19.8, respectively; and absolute reductions in total lesion counts were 38.2 and 33.9, respectively. In both severity groups, the efficacy of clindamycin-BPO 2.5% was statistically significant compared with vehicle ($P < .001$). Treatment success, as judged by a 2-grade improvement in global severity relative to baseline, was 45.5% in the severe acne group and 32.3% in the moderate acne group. In both cases, results were statistically significant compared with vehicle ($P \leq .001$). Three times as many subjects with severe acne treated with clindamycin-BPO 2.5% were "clear" or "almost clear" at week 12 (as judged by a 3- or 4-grade improvement in global severity relative to baseline) compared to those treated with vehicle
($P = .005$).

Conclusions: The unique fixed combination of clindamycin-BPO 2.5% aqueous gel once daily is an effective therapy for the management of subjects with severe inflammatory and noninflammatory acne. Clindamycin-BPO 2.5% aqueous gel provides comparable efficacy in this patient group to those with moderate acne and a realistic option in the management of severe acne.

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P719

Comparison of the tolerability of benzoyl peroxide microsphere wash versus a gentle cleanser, when used in combination with a clindamycin and tretinoin gel: A multicenter, investigator-blind, randomized study

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In clinical practice, a major challenge encountered with acne is irritation related to topical medications used for treatment. It remains an important priority for the practitioner to identify treatment regimens that combine efficacy with favorable tolerability and cosmetic acceptability. Advances in topical vehicle technology have enabled the development of newer formulations that are designed to deliver active ingredients with improved cutaneous tolerability profiles. Recently, a wash that incorporates patented microsphere technology has been developed to deliver benzoyl peroxide in a vehicle formulated to maintain a favorable tolerability profile. The focus of this investigation is to evaluate the tolerability of benzoyl peroxide microsphere (BPM) wash 5.5% in combination with a clindamycin and tretinoin gel versus a gentle cleanser and a clindamycin and tretinoin gel in acne vulgaris. Subjects at least 12 years of age with mild to moderate facial acne were randomized (1:1) to receive once daily treatment with one of the cleansers (BPM wash or gentle nontherapeutic cleanser) and a clindamycin 1.2% and tretinoin 0.025% combination gel for 21 days. Tolerability assessments of the signs (erythema, dryness, and scaling) and symptoms (burning/stinging and pruritus) were performed at days 0, 14, and 21. Subject satisfaction regarding the therapy regimen and aesthetic attributes of the cleansers were assessed at day 21. Thirty-one male and female subjects 12 to 46 years of age with mild to moderate facial acne were enrolled and completed the study. Both treatment groups exhibited good local cutaneous tolerability; mean/median scores for signs and symptoms either improved or had no change for the majority of subjects. There were no statistical differences among the two regimens in erythema, dryness, scaling, burning/stinging, or pruritus (all $P \leq 0.16$). There were no treatment-related adverse events reported in either group. Similar proportions of subjects in the BPM wash and gentle cleanser groups reported excellent or good overall experience with the regimens, 14 of 15 and 16 of 16, respectively. BPM wash rated highly in aesthetic attributes, including creaminess, gentleness, moisturizing, and postrinse softness. In this study, BPM wash offered the same tolerability profile as a gentle cleanser when used in conjunction with a combination antibiotic and retinoid product and was rated very favorably by subjects in overall treatment experience and aesthetic attributes.

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Exploration of adherence behavior in teenagers with acne vulgaris: A randomized controlled trial

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Nonadherence to topical medications is a potential obstacle to the successful treatment of acne. We completed a small exploratory study to assess teenagers' adherence to once daily topical acne treatment and to investigate potential interventions to improve adherence in acne patients.

Patients 13 to 18 years of age with moderate to severe acne were treated with adapalene 0.1% gel once daily for 12 weeks, with randomization to one of four intervention groups (more frequent visits, electronic reminders, parental reminders, or no intervention). Adherence was monitored via electronic Medication Event Monitor Systems (MEMS) caps, product weights, and self-report. The median adherence over 12 weeks was 54% for the no intervention group, 80% for the "more frequent doctor visits" group, 55% for the "electronic reminders" group, and 37% for the "parental reminders" group. Teenagers are not fully compliant with their acne treatment regimens. Our results point to potential targets for improving adherence outcomes.

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P721

Treatment of acne: Photodynamic therapy and micropeeling

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Emerging problems with conventional antibiotic, retinoid, and hormonal acne treatments and their related side effects have created a demand for safer treatments. The aim of this study was to evaluate the efficacy of a new acne treatment protocol based on aminolevulinic acid-photodynamic therapy (ALA-PDT) and micropeeling. After undergoing the appropriate washout of any previous treatment, 50 patients with mild to moderate inflammatory facial acne applied a micropeeling lotion containing glycolic and salicylic acid every night for 2 weeks, after which two ALA-PDT sessions were scheduled separated by a period of 2 weeks. A polyethylenglycol ointment containing 5% ALA was applied under occlusion for 2 hours and 75 J/cm^2 of red light (630 nm) was administered in 8 minutes using a bifacial diode lamp, irradiance 160mW at 50 mm. One week after the PDT session, the patients resumed the topical micropeeling treatment. Each patient's acne was visually assessed by a spot count of inflammatory and noninflammatory lesions at baseline and after 1, 3, and 6 months of treatment. The acne scores of all of the patients progressively decreased in proportion to their baseline scores. The mean percentage reductions in inflammatory lesions after 1, 3, and 6 months were 62%, 84%, and 96%, respectively. The adverse effects were transient erythema after the PDT sessions. ALA-PDT and micropeeling are effective in reducing mild to moderate acne. ALA-PDT promptly reduces inflammatory acne lesions but is scarcely efficient against comedons and microcysts, which require micropeeling. In our experience, the combination of ALA-PDT and micropeeling is more efficient than conventional therapies in cases of mild and moderate acne.This new drug-sparing treatment can be considered an advance in the treatment of acne.

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