

Acne

P100

Comparing a novel solubilized benzoyl peroxide gel with benzoyl peroxide/clindamycin: Final data from a multicenter, investigator-blind, randomized study

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Introduction: A newly developed treatment for acne—a novel solubilized 5% BPO gel—is now available as a stand-alone product and as part of a 3-step acne system. In other BPO products, the poor solubility of BPO can result in the formation of BPO macrocrystals and, as a result, suboptimal bioavailability and follicular penetration. However, the novel solubilized BPO gel formulation is designed to maintain the BPO in solution—offering the potential for enhancing both the bioavailability and follicular penetration of BPO.

Methods: Patients were eligible for enrollment if they were 11-45 years old and had moderate facial acne vulgaris (25-100 comedos, 25-100 inflammatory lesions, and up to 2 nodulocystic lesions). Patients were randomly assigned to apply solubilized 5% BPO gel to one facial side and a 5% BPO/1% clindamycin combination product to the other facial side, twice daily for 4 or 12 weeks.

Results: A total of 65 patients enrolled. A significantly greater reduction in non-inflammatory lesion count was observed with the solubilized BPO gel compared with BPO/clindamycin at weeks 1, 2, 3, 4, and 12 ($P \leq .05$). At week 12, the reduction in non-inflammatory lesion count was 57% versus 46% ($P \leq .05$) in the solubilized 5% BPO gel and BPO/clindamycin groups, respectively. Reductions in inflammatory lesion count were comparable between groups at all timepoints. In the initial weeks of treatment, mean levels of erythema, dryness, peeling, stinging/burning, and itching were significantly higher with the solubilized BPO gel than with BPO/clindamycin. However, the difference was likely not clinically significant because mean levels were consistently less than mild in both groups and patients' level of satisfaction with the improvement in their acne was comparable between groups.

Conclusions: The solubilized 5% BPO gel was associated with significantly greater reductions in non-inflammatory lesion count than 5% BPO/clindamycin. The additional efficacy of the solubilized BPO gel is likely attributable to enhanced follicular penetration of BPO. The unique solvent technology used in the BPO formulation could also be involved. The solubilized BPO gel has two key clinical advantages over BPO/clindamycin—its clinical efficacy is achieved in the absence of an antibiotic, and a significantly greater reduction in the non-inflammatory lesion count may be evident after only 1 week.

Commercial Support: OMP, Inc.

Acne

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Antimicrobial activity of 2-tert-butylhydroquinone (TBHQ) and bismuth or copper, new synergistic combinations for the treatment of acne

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Acne affects a majority of the adolescent and young adult population. It is a multifactorial disorder associated with *Propionibacterium acnes* infection of functionally blocked pilosebaceous follicles. Commonly treated with topical antibiotics, concerns regarding increasing resistance have led to the need for alternative anti-infectives. 2-tert-butylhydroquinone (TBHQ) is a lipophilic sterically hindered hydroquinone often used as an antioxidant in foodstuffs rich in fats or oils. The antimicrobial properties of TBHQ against food-related bacteria are well known but the compound's pronounced activity against propionibacteria is a recent discovery [WO-2006/100496]. Under appropriate conditions, TBHQ can be oxidised to 2-tert-butylbenzoquinone (TBBQ) with which it exists in a redox couple. The oxidation reaction proceeds in two stages via a semiquinone intermediate resulting in free radical generation. At neutral to acidic pHs, the reaction occurs slowly but can be catalysed by transition metal ions such as copper. In order to determine whether this mechanism could boost the antimicrobial activity of TBHQ, we compared the potency of TBHQ in the presence and absence of two metal salts. Using a modified disk diffusion assay (DDA), TBHQ in combination with either copper sulphate (CuSO₄), or bismuth subsalicylate (BiSS), a non-transition metal salt, markedly increased the mean zone of inhibition (ZOI) above that of the most active compound alone against *Propionibacterium acnes* NCTC737. Mean ZOIs from triplicate assays increased by 11.68 mm (50.3% area increase) in combination with CuSO₄ and by 10.83 mm (129.6% area increase) with BiSS. Similar levels of potentiation in modified DDAs were observed using different copper and bismuth salts. The potentiation of TBHQ with either CuSO₄ or BiSS versus *P. acnes* was confirmed against a panel of antibiotic susceptible and resistant propionibacterial strains. Checkerboard fractional inhibitory concentration (FIC) assays showed the interaction of TBHQ with CuSO₄ or BiSS against *P. acnes* to be synergistic with lowest FIC indices of 0.5 and 0.31 respectively (synergy = FICI ≤ 0.5). Synergistic combinations of TBHQ with copper or bismuth offer a novel antimicrobial treatment for acne against which bacterial resistance would be unlikely to develop.

Commercial Support: Authors are employees of Syntopix Group plc

Acne

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A phototracking study documenting the clinical usefulness of a 3-step acne system containing solubilized benzoyl peroxide for normal to dry skin

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Introduction: Benzoyl peroxide (BPO) has poor solubility and tends to aggregate into clusters, thereby hindering its bioavailability and its follicular penetration. A 3-step acne system has been developed that contains a novel solubilized 5% BPO lotion and which aims to enhance the bioavailability and follicular penetration of BPO. Results from an investigator-blind randomized trial have demonstrated comparable reductions in non-inflammatory and inflammatory lesion counts with the 3-step acne system for normal to dry skin relative to a combination BPO/clindamycin product. The present study documents photographically the clinical improvements attainable with the 3-step acne system.

Methods: Patients were eligible to enroll in this phototracking study if they had at least 25 acne lesions, including at least 10 inflammatory acne lesions. All patients treated themselves for 8 weeks using the 3-step acne system for normal to dry skin (which comprises a proprietary gentle cream cleanser, a solubilized 5% BPO lotion, and a therapeutic moisturizer containing 20% glycerin and 1% dimethicone). They were instructed to: wash their face twice daily with the cream cleanser and allow 10 minutes for the skin to dry completely; apply one pump of the solubilized 5% BPO lotion once daily and allow the lotion to absorb into the skin completely; and apply the therapeutic moisturizer as needed. If going outside, they were requested to then also apply a sunscreen.

Results: A total of 10 patients (7 females, 3 males) were evaluated. The patients were 12 to 28 years of age (mean, 19 years) and had Fitzpatrick skin types I-IV (10% I, 20% II, 50% III, 20% IV). Four of the patients were considered to have sensitive skin at baseline. At the end of the study, 9 of the 10 patients showed a reduction in non-inflammatory lesion count (median 52% reduction) and 9 of 10 patients showed a reduction in inflammatory lesion count (median 63% reduction). At the end of the study, the overall acceptance of the tolerability of treatment was rated as excellent in 6 patients, good in 3, and fair in 1. The patients reported their satisfaction with the treatment regimen to be very satisfied (5 patients), satisfied (4 patients), or dissatisfied (1 patient who was thought to develop contact dermatitis).

Conclusions: The 3-step acne system is an effective and well tolerated antibiotic-free treatment for acne, and results in high levels of patient satisfaction.

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Acne

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Development and validation of a method for assessing post-inflammatory hyperpigmentation (PIH)

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Introduction: Post-inflammatory hyperpigmentation (PIH) results in skin darkening and discoloration that appear as spots or as large patches on a person's body. The PIH is more common in people with highly pigmented skin. The objective of this study was to develop a standardized method for the evaluation of PIH caused by acne.

Methods: This was an open-label, non-randomized, multicenter, community-based, Phase IV study of 544 acne male and non-pregnant, non-lactating female patients who were treated with tretinoin (either 0.04% or 0.1% formulation). Patients with Fitzpatrick skin types I and II were excluded from analysis. The PIH was assessed via photographic imaging techniques, which included different camera filters (fluorescence [FLUO], parallel-polarized [PPOL], ultraviolet [ULVI], visible [VISI], and cross-polarized [XPOL]), lighting conditions, and camera angles. A facial map was constructed to capture all 7 areas of the face.

Results: Of the 502 patients who completed the tretinoin study, 86 patients had photographs taken and analyzed. Of those 86 patients, 57 patients had a Fitzpatrick skin type between III and V. The FLUO photographs displayed Propionibacterium acnes and open comedones too prominently, and variability in lighting between patients. The ULVI photographs displayed low clarity and poor contrast of melanin. The XPOL photographs were deemed the best choice as they displayed subsurface features and were glare-free. The 684 XPOL full-face photographs were expanded to 1596 region-cropped photographs and then analyzed, which resulted in 100 region-cropped photographs from 20 subjects for grading.

Conclusions: The XPOL photographs were considered the best to use in a facial mapping system in the evaluation of PIH.

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Acne

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“Got sick, got a gift”: a new therapeutic strategy for the adolescent acne treatment

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Background: Acne vulgaris is a common disease among adolescents and may have several effects on their psychological status. For many adolescents, this dermatosis elicits negative emotional reactions including: depression, anxiety, anger, frustration, helplessness, decreased well-being and self-esteem, and suicidal ideation. Although there are substantial studies on the pathogenesis, clinical features, psychosocial impact and treatment of acne, there is an inadequacy of information about the knowledge provided by different sources as mass media, doctors, parents and friends. This situation can lead to patients' ongoing misconceptions on the perception and understanding about their acne condition. Taking into consideration that this state can make adolescents with this disease feel guilty about having acne and this feeling can make acne psychosomatic effects more severe, it is important to develop new therapeutic programs to increase adolescent awareness and understanding of their condition in order to enhance patient adaptation and compliance with treatment.

Objective: The aim of the present study is to evaluate the effects of an educational purpose based on the theme “got sick, got a gift” as therapeutic strategy on adolescent acne treatment.

Material and Methods: 100 teenagers from private dermatological clinics in Brazil with acne vulgaris (grade I-IV) were enrolled in this study. All individuals answered a questionnaire form composed by general questions, including knowledge, beliefs, and perceptions of patients with acne, and the interference of the theme above on adolescent behavior in relation to acne, i.e., evaluating whether or not this purpose (“got a gift”) is able to cause any change in patients' behavior, attitude, thoughts and feelings about the disease.

Results: Results show high level of ignorance and misinformation, high levels of stress, hope in home treatments, resistance both to doctors' appointments and compliance with treatment.

Conclusion: The correct conformity to the treatment and its understanding may be achieved through a therapeutic program model presented as a gift (as the motto suggests “Got sick, Got a gift”) being attractive and seductive, including information about the treatment, its difficulties and limitations – and suggesting an ideal attitude to beat, control and cure this disease.

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Acne

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Meta-analysis of randomized controlled trials using benzoyl peroxide and clindamycin topical treatments in acne

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Topical benzoyl peroxide (BPO) plays an important role in antimicrobial acne treatment. We sought to compare a newly formulated solubilized 5% BPO (sBPO) against existing 5% BPO, 1-1.2% clindamycin (CL) and combination BPO/CL products in reducing acne lesions. A meta-analysis following the Cochrane collaboration guidelines in accordance with the PRISMA statement was conducted. Data sources included the PubMed database from 1987 to the present, FDA summaries for the basis of drug approval, and posters and unpublished statistical analyses of studies where available. We included randomized controlled trials (RCTs) that treated subjects with either 5% BPO, 1-1.2% CL or combination BPO/CL. Studies included endpoints of actual lesion reduction and/or percent lesion reduction of inflammatory and/or non-inflammatory lesions at 2-4 weeks and/or 10-12 weeks. We retrieved 124 potential RTCs under our search criteria. After review, 23 RTCs met all inclusion and exclusion criteria and were deemed valid to include in our meta-analysis. Data was grouped by type of topical treatment and endpoint (5% sBPO: n=4 studies, s=210 subjects, 5% BPO: n=10, s=824, 1-1.2% CL: n=14, s=3143, combination BPO/CL: n=15, s=1923, placebo: n=9, s=1308). We calculated the overall mean percent reduction and actual reduction in inflammatory and non-inflammatory lesion counts at 2-4 and 10-12 weeks. After 2-4 weeks, the 5% sBPO regimen had statistically greater percent lesion reductions over all other groups with non-overlapping 95% confidence intervals (weighted mean inflammatory lesion reduction: sBPO = 55.2%, BPO = 33.4%, BPO/CL combination = 40.7%, CL = 21.5%, placebo = 7.3%; weighted mean non-inflammatory lesion reduction: sBPO = 42.7%, BPO = 19.1%, BPO/CL combination = 26.2%, CL = 10.0%, placebo = 6.6%). At 10-12 week endpoints, 5% sBPO and combination products were similar, with overlapping confidence intervals. However, there were only two completed studies with 5% sBPO that extend 10-12 weeks (weighted mean inflammatory lesion reduction: sBPO = 51.8%, BPO = 43.7%, BPO/CL combination = 55.6%, CL = 45.9%, placebo = 26.8%; weighted non-inflammatory lesion reduction: sBPO = 47.7%, BPO = 30.9%, Combo = 40.3%, CL = 32.6%, placebo = 17.0%). Actual lesion reductions were not statistically different. We conclude that the new 5% sBPO has an equal to superior lesion reduction profile compared to other BPO products, combination BPO/CL products and topical CL products.

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Acne

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Susceptibility of propionibacterium acnes in the presence of sebum to NB-00X formulations

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Background. Antibiotic resistance has become an enormous clinical problem in the treatment of acne. NB-00X is an antimicrobial oil-in-water emulsion with an average droplet diameter of 180 nm and a composition that allows for selective penetration into the pilosebaceous unit, the site of acne pathogenesis. The mechanism of action of NB-00X is physical via membrane destabilization, making the emergence of resistance improbable. This study sought to determine the susceptibility of *P. acnes* to NB-00X formulations in the presence of sebum, a major component of the pilosebaceous unit and a nutrient source for *P. acnes*.

Methods. Sixteen clinical isolates of *P. acnes* with defined resistance mechanisms to erythromycin, clindamycin and/or tetracycline were used. Antimicrobial susceptibility testing in microtiter broth and MBC evaluations were done in the presence and absence of 50% artificial sebum under anaerobic conditions. NB-00X was made by high speed emulsification of Tween 20, ethanol, soybean oil, cetylpyridinium chloride and water. Other formulations assessed were NB-00X containing either 0.5% benzoyl peroxide (NB/BPO) or 2% salicylic acid (NB/SA).

Results. NB-00X was bactericidal for all strains of *P. acnes* with MIC₉₀/MBC₉₀ values of 0.5/2 µg/ml in the absence of sebum. The MIC₉₀/MBC₉₀ values in the presence of 50% sebum increased to 128/1024 µg/ml. A reduction in the MBC₉₀ for NB-00X occurred when BPO or SA was integrated into the formulation, resulting in a MIC₉₀/MBC₉₀ of 128/256 µg/ml. The MIC₉₀/MBC₉₀ values of SA (1000/2000 µg/ml) were not significantly impacted by the presence of sebum, but the MIC₉₀/MBC₉₀ values of BPO increased eight-fold in the presence of sebum (400/1600 µg/ml).

Conclusions. NB-00X had relevant microbiological and bactericidal activity against a collection of recent clinical isolates of *P. acnes*, including multidrug-resistant strains. The combinations of NB/BPO or NB/SA were synergistic in the presence of sebum suggesting novel combinations for the treatment of acne.

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Acne

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Randomized, evaluator-blinded, parallel group comparison study of the tolerability and subject preference of a benzoyl peroxide microsphere wash compared to a gentle non-medicated cleansing wash in mild to moderate acne

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Current treatment regimens for acne incorporate a combination of therapeutic agents to target the multiple factors that fuel the disease. While effective, many anti-acne agents can also cause irritation, creating challenges in finding an efficacious and tolerable treatment regimen. Benzoyl peroxide has been widely used for acne treatment due to its antimicrobial effect on *P. acnes*, associated reduction of inflammatory lesions, as well as, its advantage over antibiotics, with no reports of bacterial resistance. However, cutaneous irritation can be a primary limitation of benzoyl peroxide treatments. To provide the therapeutic benefits of benzoyl peroxide while maintaining favorable tolerability, a new wash formulation has been developed that incorporates patented microsphere delivery technology.

A single-center, randomized, evaluator-blinded, parallel group comparison study was conducted to evaluate the tolerability and subject preference of 7% benzoyl peroxide microsphere wash compared to a non-medicated gentle cleansing wash. Subjects at least 18 years of age with mild to moderate facial acne were randomized (1:1) to receive once daily treatment with one of the washes (BP or gentle) for 21 days. Tolerability assessments of objective (erythema, edema and scaling/dryness) and subjective (burning/stinging, itching) irritation were performed at baseline and Day 21. Subject satisfaction and product aesthetics were also evaluated.

Forty-six male and female subjects aged 18 to 58 years with mild to moderate facial acne completed the study. Both treatment groups demonstrated very favorable cutaneous tolerability; mean scores for those irritation parameters measurable at baseline were minimal and improved during the course of the study. Furthermore, no statistical differences were found when comparing the BP and gentle wash groups in all irritation parameters (all $P > 0.32$). Both products were well-tolerated over the 21 day trial and no treatment-related adverse events were reported. Identical proportions, 83%, of subjects in the BP and gentle wash groups reported excellent or good overall experience. The aesthetic attributes of the BP wash were highly rated, including gentleness, creaminess, non-grainy and pleasant consistency/texture. Results show this new 7% benzoyl peroxide microsphere formulation demonstrated the same tolerability profile as a non-medicated gentle cleansing wash, and was highly rated in aesthetic attributes and overall treatment experience.

Commercial Support: 100% is sponsored by SkinMedica, Inc.

Acne

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Once daily application of a fixed combination clindamycin phosphate (1.2%) and benzoyl peroxide (2.5) gel results in clinically meaningful improvements in health related quality of life (HRQL) in patients with moderate to severe acne vulgaris

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Background: The impact of acne on health related quality of life (HRQL) can be as profound as other chronic diseases. Acne treatments may differentially impact HRQL due to varying efficacy and tolerability. Thus, HRQL is an important endpoint in comparative clinical trials of acne treatments. Studies have demonstrated that a combination of clindamycin phosphate 1.2% and benzoyl peroxide 2.5% (clindamycin-BPO 2.5%) gel applied once daily is well-tolerated and significantly reduces the number of inflammatory and non-inflammatory lesions compared with each individual active ingredient.

Objective: To assess the effectiveness of clindamycin-BPO 2.5% gel in comparison with each individual active ingredient in improving acne-specific HRQL in patients with moderate to severe acne.

Methods: Two identical, double-blind studies were conducted in 2813 patients with moderate to severe acne to establish the safety and efficacy of clindamycin-BPO 2.5% gel. HRQL was assessed at baseline and Week 12 using the Acne Specific Quality of Life Questionnaire (Acne-QoL). The Acne-QoL assesses 4 HRQL domains: self-perception, role-emotional, role-social and acne symptoms. The primary endpoint for the intent to treat analyses was the absolute change from baseline to Week 12 on the 4 Acne-QoL domains. The minimal clinically important difference was calculated using patient and physician anchors.

Results: Patients treated with clindamycin-BPO 2.5% gel had significantly greater improvements on each of 4 Acne-QoL domains compared to each group of patients treated with the individual active ingredients ($p < 0.001$), although the absolute differences were small. The absolute change from baseline (7.1 for role-emotional, 5.6 for role-social, 8.5 for self-perception and 7.2 for acne symptoms) for patients receiving clindamycin-BPO 2.5% gel exceeded the patient- and physician-based MCIDs. A greater proportion of patients treated with clindamycin-BPO 2.5% gel had a clinically meaningful change on the 4 Acne-QoL domains than patients treated with each individual active ingredient ($p < 0.01$).

Conclusion: Significantly more patients with moderate to severe acne treated with clindamycin-BPO 2.5% gel had clinically meaningful improvements in acne-specific HRQL than patients treated with each individual active ingredient. Thus, clindamycin-BPO 2.5% gel is not only an effective treatment for acne patients, but also results in clinically meaningful improvements in HRQL.

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Acne

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Novel follicular-targeted nanoemulsions for acne

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Background: The pilosebaceous unit plays an important role in permeation and as a potential reservoir of topically applied compounds. We have previously shown that fluorescently-loaded nanoemulsions specifically target the pilosebaceous units and can traverse laterally to disease areas in the skin. Penetration of the nanoemulsion in the skin depends on various formulation variables. We investigated formulation variables to achieve adequate delivery into the skin to kill *Propionibacterium acnes*.

Methods: In vitro skin permeation studies with several different NB-00X formulations (e.g., lotions and gels) were performed using diffusion cells. Two NB-00X formulations containing benzoyl peroxide (BPO) and salicylic acid (SA) were compared to commercial products. Twelve and 24 hours after topical application, the residual test articles were removed and the epidermis and dermis were assayed for the nanoemulsion marker, cetylpyridinium chloride (CPC) and/or the anti-acne active (BPO/SA) by HPLC or HPLC/MS/MS.

Results: There was an increase in the delivery of CPC to the epidermis and dermis with increasing concentrations of nanoemulsion formulations, as expected, at 24 hours. At the 12-hour time point, the gel formulations delivered two-fold higher levels of CPC into the epidermis, indicating a faster rate of delivery. The dermal levels were similar at either time point. The amounts of CPC found in the receptor compartment at 12 and 24 hours were below the level of detection for all formulations. Specific delivery and controlled release of BPO and SA into the hair follicles from the nanoemulsions were demonstrated. The penetration results indicated that the BPO and SA can be transported in the skin via the follicular route to greater levels than the commercial products at the same concentrations. Transmission electron microscopy studies show that the NB-00X formulations are cidal, with a kill-on-contact mechanism. Within 10 minutes, there was total killing of a multidrug-resistant *P.acnes* isolate.

Conclusions: These data suggest that nanoemulsions, with their unique structure, size and composition, have inherent anti-acne properties and target the pilosebaceous units in skin. These findings suggest that follicular targeting via nanoemulsions may also be a promising tool in topical acne therapy.

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Acne

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Treatment of mild to moderate truncal acne with benzoyl peroxide 8% creamy wash plus clindamycin phosphate foam 1% with and without doxycycline

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Objectives: Oral antibiotics are commonly prescribed in the management of truncal acne, and most appropriately in combination with a topical regimen. There is limited data available on the combined use of topical and systemic medications for the treatment of truncal acne. The objective of this study was to evaluate the utility of adding an oral antibiotic to a topical regimen for the treatment of mild to moderate truncal acne.

Methods: A multicenter, investigator-blinded, randomized, parallel design pilot study was conducted to assess the efficacy and safety of clindamycin phosphate foam 1% plus benzoyl peroxide (BPO) 8% wash versus clindamycin phosphate foam 1% plus benzoyl peroxide (BPO) 8% wash and doxycycline 100mg daily. Subjects were instructed to apply the BPO wash while in the shower/bath and the clindamycin foam immediately following the shower/bath each morning. The treatment period was for 16 weeks with evaluations at baseline, weeks 4, 8, 12 and 16. Investigator evaluations included inflammatory, non-inflammatory and nodule lesion counts on the chest and back, global severity scores, and peeling, erythema and dryness severity scores. Subject assessments included pruritus and burning severity scores, skin comfort scores, and treatment regimen compliance. Safety assessments were monitored by adverse event reporting.

Results: Thirty-three subjects with mild to moderate truncal acne were enrolled and 22 subjects completed the study. Median percentage reductions in lesion counts of -16.09% and -23.77% were achieved at Week 4 with BPO/clin and BPO/clin/doxy regimens, respectively; inter-group differences were non-significant. At week 16, median percentage reductions in lesion counts of -36.32% and -43.90% were observed with BPO/clin and BPO/clin/doxy regimens, respectively; inter-group differences remained non-significant. Both treatment regimens were well tolerated and there were no serious adverse events over the course of the study.

Conclusions: Both treatment regimens achieved a comparable reduction in lesion counts. These data suggest that the addition of doxycycline 100mg QD to a clindamycin phosphate foam 1% plus benzoyl peroxide (BPO) 8% wash topical regimen may not provide additional benefit in the management of mild to moderate truncal acne.

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