

Efficacy of Benzoyl Peroxide (5.3%) Emollient Foam and Benzoyl Peroxide (8%) Wash in Reducing *Propionibacterium acnes* on the Back

James J. Leyden MD

Department of Dermatology, University of Pennsylvania, Philadelphia, PA

ABSTRACT

Background: Topical treatment of acne vulgaris on the back is challenging largely due to the extensive broad surface with difficult to reach areas. A “leave-on” foam is suited for application to the trunk due to ease of application and spreadability. Prior to this trial, no data on *Propionibacterium acnes* (*P. acnes*) reduction on the back has existed for any benzoyl peroxide (BP) formulations or other acne treatments.

Objectives: To evaluate the effectiveness of BP (5.3%) emollient foam and BP (8%) wash in reducing *P. acnes* levels on the back.

Methods: Five-week open-label single-center study of 20 healthy subjects (>18 years old), colonized with *P. acnes* on their backs (>10,000 colonies per cm²). Subjects were treated once daily with BP (5.3%) foam for two weeks; no treatment in week 3, and BP (8%) wash once daily for two further weeks. Quantitative bacteriologic cultures obtained at baseline and weeks 1, 2, 3, 5 and 6.

Results: Nineteen evaluable patients. Total *P. acnes* counts were reduced by 1.9 log (one week) and 2.1 log (two weeks) with BP (5.3%) emollient foam. BP (8%) wash did not reduce *P. acnes* counts after two weeks.

Discussion: BP (5.3%) emollient foam was superior to BP (8%) wash in reducing *P. acnes* on the back. The lack of effect of BP (8%) wash is surprising in view of the demonstrated results on the face and warrants further study.

INTRODUCTION

The effectiveness of topical acne therapy is related to adherence with the regimen by the patient, which is influenced directly by the ability to apply anti-acne preparations appropriately. Although truncal acne is less well studied than facial acne, there has been increasing attention on its evaluation and management.^{1,2}

Most patients with truncal acne present with concurrent facial acne: a study of truncal acne demonstrated that 48 percent of patients had acne solely on the face while 52 percent also had truncal acne.¹ Only two percent of patients had solely truncal acne. In a more recent study of patients referred by primary care physicians to dermatologists for the treatment of acne, the prevalence of facial acne was 93 percent while the prevalence of chest and back acne was 45 and 61 percent, respectively.³

Topical treatment of truncal acne presenting on the chest, back and shoulders can be challenging as it requires application of anti-acne preparations to a difficult to reach, broad surface area. In addition, there is no effective treatment for truncal acne scarring once it develops, so effective acne therapy is important to prevent lesion development and scar formation.⁴

Due to the extensive surface area of the back, it is important that the appropriate vehicle be selected that can be conveniently and efficiently applied. Formulations that exhibit ease of

spreadability and lack of residue, such as cleansers and foams, may be more applicable for truncal application.^{5,6}

Benzoyl peroxide (BP) is extensively utilized as a topical agent for the treatment of acne.⁷ BP alone or in combination with clindamycin reduces *Propionibacterium acnes* (*P. acnes*) and reduces the emergence or proliferation of antibiotic-resistant *P. acnes* strains.⁷⁻⁹ Importantly, *P. acnes* organisms resistant to BP have not been identified nor would it be expected since this agent is a non-antibiotic antimicrobial.⁷

BP exerts its therapeutic effect in acne through reduction of *P. acnes* as demonstrated by a 1.0–2.0 logarithmic colony reduction on the face. “Leave-on” BP formulations have been shown to provide greater reduction in *P. acnes* than “wash-off” formulations.^{10,11} BP “wash-off” formulations have been shown to be effective in reducing *P. acnes* populations on the face.^{12,13} Interestingly, the author could find no published data on *P. acnes* reduction on the back for any BP formulation.

“Wash-off” formulations of BP are frequently recommended for the treatment of truncal acne due to patient convenience of application in the shower as well as to minimize bleaching potential.^{14,15}

The purpose of this study was to evaluate the in vivo effects on *P. acnes* levels on the back with use of a BP (5.3%) emollient foam and a BP (8%) wash by quantitative microbiologi-

cal determinations. In addition, the study evaluated adverse events and tolerability associated with the two preparations used on the back.

METHODS

This five-week, open-label single-center study enrolled 20 healthy adults (≥ 18 years old) who were free of acne but had high *P. acnes* populations on their backs (at least 10,000 colonies per cm^2). Subjects were screened to ensure that none were using any form of topical or systemic antibiotics within four weeks prior to enrollment. They were instructed not to use any antimicrobial topical products (e.g., soaps, medicated shampoos, acne preparations).

Key inclusion criteria included: healthy, adult male and/or female volunteers 18 years of age and older; all females must be using an acceptable method of contraception; subjects willing to refrain from using antimicrobial topical products (shampoos, soaps, acne preparations). Key exclusion criteria included: any volunteer who exhibited any skin disorders of an acute or chronic nature including psoriasis, eczema, etc.; use of topical or systemic antibiotics within the previous four weeks; females who were pregnant, planning a pregnancy or breastfeeding.

Each subject was treated once daily with BP (5.3%) emollient foam during the first two weeks at the study center under supervision by a technician on weekdays and unsupervised at home over the weekends. The area treated was from just below the scapulae to the shoulders. A cherry tomato-sized amount of foam was spread over this area. Subjects received no treatment in week 3 to allow bacterial re-growth. Subjects were subsequently instructed to apply BP (8%) wash to the same area treated with the foam for two weeks when showering, referring to the package insert (i.e., wash until a full lather develops, rinse and pat dry using once daily the first week and twice daily the second week if more than one shower a day is needed). No specific instructions regarding the amount of wash product were given.

Quantitative bacteriologic cultures using a modified Williamson and Kligman^{16,17} scrub technique were obtained from the upper back at baseline and weeks 1, 2, 4, 5 and 6. Colony forming units (CFU) of *P. acnes* were counted at a dilution that contained between 10 and 100 CFU. Total densities of *P. acnes* (\log_{10} CFU per cm^2) were calculated and reported.

Cutaneous tolerability assessments were carried out during the first two weeks and at the weekly visits during the last two weeks of the study. Local signs and symptoms (scaling, dryness, erythema, itching and stinging) were assessed on a four point scale where 0=none, 1=mild, 2=moderate and 3=severe.

RESULTS

Nineteen out of 20 subjects were evaluable.

Efficacy

At baseline, the mean *P. acnes* count was \log_{10} 6.43 ± 0.27 per cm^2 . Total *P. acnes* counts were reduced by 1.93 log after one week of treatment, and by 2.1 log after two weeks of treatment with BP (5.3%) emollient foam.

One week after discontinuation of the BP (5.3%) emollient foam the mean *P. acnes* count was \log_{10} 5.81 ± 0.73 per cm^2 , a statistically lower value than at baseline indicating a substantive effect of the BP (5.3%) emollient foam. Total *P. acnes* counts showed no reduction from this new baseline after one or two weeks treatment with BP (8%) wash (Figures 1 and 2, and Table 1).

Tolerability

No serious adverse events were reported with either treatment. No erythema, dryness, scaling or burning were observed or re-

FIGURE 1. Effect of BP (5.3%) emollient foam and BP (8%) wash on populations of *P. acnes* on the back.

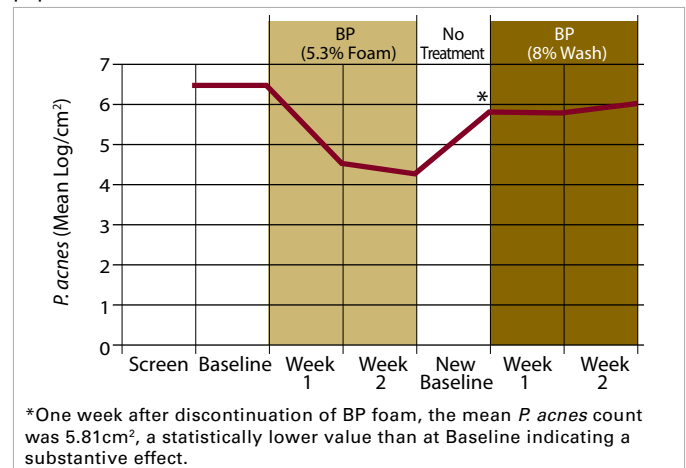


FIGURE 2. Change from baseline in *P. acnes* counts with BP (5.3%) foam and BP (8%) wash.

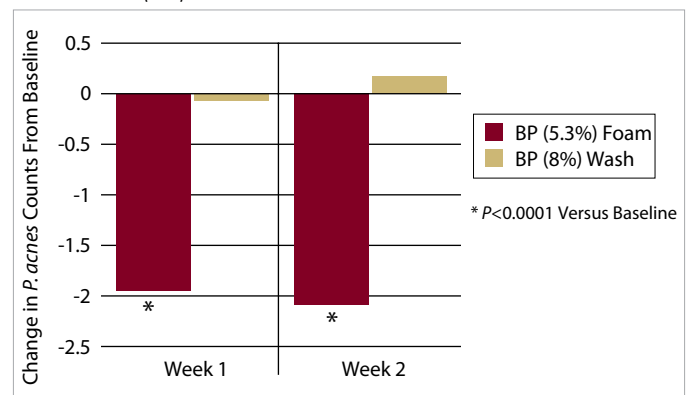


TABLE 1.

Effect of BP (5.3%) Emollient Foam and BP (8%) Wash on Populations of *P. acnes* on the Back—Individual Subject Data, Mean and Standard Deviation [*P. acnes* (Mean Log/cm²)]

Subject	Base	Wk 1	Wk 2	New Base	New Wk 1	New Wk 2	Net Change From Baseline			
		BP (5.3%) Emollient Foam			BP (8%) Wash		Wk 1	Wk 2	New Wk 1	New Wk 2
1	6.35	5.84	5.28	6.23	6.44	6.55	-0.51	-1.07	0.21	0.32
2	6.37	4.59	4.00	5.81	4.87	5.84	-1.78	-2.37	-0.95	0.03
3	6.50	5.06	4.24	5.84	6.11	6.53	-1.44	-2.26	0.27	0.69
4	6.66	4.59	5.19	6.47	6.27	6.46	-2.07	-1.47	-0.20	-0.01
5	6.13	5.02	5.11	6.19	5.84	5.69	-1.11	-1.01	-0.35	-0.50
6	6.57	3.39	4.15	6.32	6.22	6.31	-3.18	-2.43	-0.11	-0.01
7	5.65	1.65	2.69	3.59	3.90	5.04	-4.00	-2.96	0.32	1.45
8	6.68	5.54	4.30	6.20	5.80	6.40	-1.14	-2.38	-0.40	0.19
9	6.57	4.00	3.74	6.09	5.10	6.60	-2.58	-2.84	-1.00	0.50
10	6.41	5.15	5.11	5.59	6.23	5.72	-1.26	-1.29	0.64	0.14
11	6.41	4.69	4.13	5.72	6.06	5.48	-1.72	-2.29	0.34	-0.25
12	6.47	3.04	3.15	5.90	5.93	6.64	-3.43	-3.32	0.03	0.74
13	6.25	3.84	3.81	5.90	5.11	5.39	-2.41	-2.44	-0.79	-0.51
14	6.92	5.54	5.39	6.39	6.41	6.65	-1.38	-1.53	0.02	0.26
15	6.38	5.69	5.04	6.48	6.36	6.76	-0.69	-1.34	-0.12	0.27
16	6.35	3.78	3.69	4.90	5.77	4.87	-2.57	-2.66	0.87	-0.03
17	6.54	4.95	4.87	5.95	6.00	6.13	-1.59	-1.67	0.05	0.18
18	6.13	3.59	3.72	4.59	5.10	5.10	-2.54	-2.40	0.51	0.51
19	6.40	5.18	5.02	6.28	6.19	6.19	-1.22	-1.38	-0.09	-0.80
MEAN	6.43	4.48	4.35	5.81	5.77	5.98	-1.93	-2.06	-0.04	0.17
STD DEV	0.27	1.07	0.78	0.73	0.67	0.62	0.95	0.69	0.51	0.51

ported with either treatment during the study. Three subjects experienced mild transient itching and one patient experienced mild to moderate transient itching during two weeks of treatment with BP (5.3%) emollient foam.

DISCUSSION

BP is frequently used as either a “wash off” or “leave on” treatment, both alone or in combination with clindamycin. The primary mode of action of this non-antibiotic antimicrobial agent is the reduction of the *P. acnes*, the organism primarily responsible for generating inflammatory lesions through. Numerous studies with various formulations have looked at the in vivo antimicrobial effect on *P. acnes* populations of BP and its combinations. “Leave on” products typically produce a 2.0 logarithm colony reduction on the face within two weeks, while one BP (6%) wash formulation produced a 1.5 log reduction after two weeks.

Interestingly, there are no in vivo studies measuring antimicrobial effects on the trunk for any formulation of BP or antibiotics

such as erythromycin or clindamycin. In this study, the in vivo antimicrobial effects of a “leave on” BP (5.3%) emollient foam formulation and BP (8%) wash formulation were compared. A cross over design permitted comparison of *P. acnes* reduction for both agents in each subject and eliminated any variation of penetration into sebaceous follicles that might occur if parallel groups had been used.

The “leave on” BP (5.3%) emollient foam produced a 2 log colony reduction after two weeks of treatment. Interestingly, there was no reduction in *P. acnes* on the trunk with the BP 8% wash. This is very surprising in view of the finding of a 1 log reduction on the face. The “leave on” product was applied under supervision in a laboratory setting while the wash product had to be used at home. Subjects were instructed to thoroughly wash the areas that had been treated with the foam. The lack of response in all subjects as opposed to response in some and failure in others argues against poor adherence. It is unlikely that an entire panel would have failed to adhere to instructions. However,

the brief exposure in a "wash off" product in an area with less density of sebaceous follicles and lipid than found on the face may not be sufficient for solubilization of BP particles in suspension in the wash formulation. Further studies with varying periods of time between application and rinsing would help clarify whether this hypothesis has merit. Likewise, it would be of interest to see how effective a "leave on" formulation is when used at home without supervision.

CONCLUSION

BP (5.3%) emollient foam effectively reduced *P. acnes* populations on the back and may offer a useful therapy for patients with acne on broad body surface areas. BP (8%) wash applied at home in the shower did not effectively reduce *P. acnes* populations on the back. Both treatments were well tolerated

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DISCLOSURES

The authors have no relevant conflicts of interest to disclose.

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ADDRESS FOR CORRESPONDENCE

James J. Leyden, MD

505 Parkway

Broomall, PA 19008

E-mail:..... jjleyden@mindspring.com