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Original Research Article

Evaluation of comedogenic potential of a moisturizer venusia max lotion (PAMA free)

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ABSTRACT

Background: Being commonly used skin care products, comedogenic potential of moisturizers should be assessed.
Aims: The aim of the study was to evaluate the comedogenic potential of a moisturizer Venusia Max Lotion (paraben-, alcohol-, mineral oil-, animal origin-(PAMA) free) when applied topically to the skin compared to the controls.
Setting and Design: Double-blind, single-center, comparative study conducted at private institute in Mumbai, India
Materials and Methods: Approximately 0.025 gm of the test product and 0.025 ml of positive control (coconut oil) and negative control (glycerin) were applied and occluded under a patch on the upper back of healthy female participants. Patch application and removal were made 12 consecutive times on alternate days for each participant. On the last day, approximately 2 hours after patch removal, a follicular biopsy was taken for all participants on all product application zones.
Statistical analysis: Data analyzed with descriptive statistics using the SPSS software version 10.0.
Results: Data from a total of 19 participants was analyzed. The mean age was 35.32 years. The mean comedone grade for Venusia Max Lotion (PAMA free) was significantly lower compared to the positive control (Coconut Oil) (1.00 vs. 2.11, respectively; P=.001). The mean comedone grade was 0.79 for negative control (Glycerine) which is nearly similar to that of the test product.
Conclusion: The moisturizer product Venusia Max Lotion (PAMA free) is non-comedogenic as compared to positive control. Thus, it can be considered for moisturizing purposes without the fear of comedogenicity.

1. Introduction

Acne vulgaris is a common chronic inflammatory disease of the pilosebaceous unit that may affect the quality of life of an individual.[1] Skin dryness or irritation may lead to disruption of the stratum corneum resulting in transepidermal water loss (TEWL), especially with the use of topical acne treatments such as benzoyl peroxide, retinoid, etc. Such TEWL may further contribute to inflammation.[2] Thus, moisturizers are recommended in addition to the primary therapy for acne.[3,4] Moisturizers assist in providing a soothing effect, prevent skin dryness, repair, and improve skin barrier function.[5] Thus, they are considered an integral part of the management of acne vulgaris.

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Avoidance of comedogenic cosmetics is essential in acne vulgaris or individuals prone to acne. Comedogenicity is a complicated process and varies depending on multiple host and environmental factors. A moisturizer can be considered comedogenic if any of its ingredients contribute to the formation of a follicular plug, trigger an allergic reaction and/or inflammation or can act as a nutrient for the growth of Propionibacterium acnes.[6] Therefore, it is crucial to evaluate cosmetics such as moisturizers for their comedogenicity. The objective of this study was to assess the comedogenic potential of a moisturizer product Venusia Max lotion (PAMA free) when applied topically under an occluded patch to the skin.

2. Materials and Methods

2.1. Design and setting

The study was a single-center, double-blinded, comparative study. After obtaining voluntary, written, signed, and dated informed consent from the participants, they were screened for eligibility in the study. Participants fulfilling the eligibility were enrolled in the study. Independent Ethics Committee at C.L.A.I.M.S. Pvt. Ltd. Andheri (W), Mumbai, approved the study. The study was conducted as per the Declaration of Helsinki, good clinical practice and local applicable regulatory guidelines concerning medical research in humans.

2.2. Participants

In this study, healthy men and women aged 18 to 55 years who had apparently healthy skin with prominent follicular orifices on the upper region of the back on visual observation were included. Also, participants who were willing to avoid intense ultraviolet (UV) exposure (sun or artificial UV) or water contact (such as swimming) or performing activities that cause sweating (such as exercise, sauna) during the study were included in the study. Participants whose job involved contact with water, their duties or activities leading to perspiration, pregnant or lactating women, any participant with scars or tattoo on the back, known hypersensitivity to any components of the study medication, taking any medical or hormonal treatment current or in the past three months by the either systemic or topical route and individuals with any clinically significant systemic or cutaneous disease that may interfere with study treatments or procedures, or those who participated in any clinical study within 30 days prior to screening were excluded.

2.3. Treatment groups

The study involved three treatment groups. First was the test product Venusia Max lotion (PAMA free) (contains shea butter, mango butter, cocoa butter, aloe butter, cetyl alcohol, stearic acid, emulsifying waxes, cyclomethicone, dimethicone, phenoxyethanol, propylene glycol, glycerin, disodium EDTA, zinc oxide and purified water). The second one was positive control (coconut oil). The third one was negative control (glycerin).

2.4. Procedures

The sites for the positive control (Coconut Oil), negative control (Glycerin), and test product (Venusia Max lotion) (3 x 3 cm^2 each) were marked on the upper back using a template. Baseline follicular biopsy of test zones was performed as follows: One to two drops of cyanoacrylate liquid adhesive was applied on the glass microscope slide. This slide was applied gently and carefully on the marked zones and the cyanoacrylate was allowed to set for 30 to 60 seconds. This slide was gently removed to yield a follicular biopsy specimen. Approximately two hours after the follicular biopsy, patch application with the controls and test product was carried out on 3 x 3 cm^2 marked zones. These were occluded using patch chambers (2 x 2 cm^2 patches). Trained study personnel carried out patch applications in all the participants. After 24 hours, the patch was removed. Adverse event and concomitant treatment checks were done. At 48 hours, the adverse event and concomitant treatment check was done again. Reapplication of the patch on the same site was performed. Weekly cycles and procedures were followed till patches are applied 12 consecutive times on alternate days for each participant. On the last day of the study, approximately two hours after patch removal, the follicular biopsy was taken for all participants on all product application zones.

2.5. Outcome assessment

The primary evaluation criteria was the grading of micro-comedones using light microscopy. In the 4-point scale used, each test product was compared with the non-treated control for the same person. Comedogenic grading was done as grade 0 being non-comedogenic; grade 1 is small microcomedones; grade 2 is moderately sized microcomedones over most of the field; grade 3 is large globoid microcomedones over the entire field.[7]

2.6. Statistical and analytical plans

Data from each participant was recorded in the case record forms and entered in Microsoft excel sheet version 16. Statistical analysis was carried out using SPSS software version 10.00. Comedogenic grading among the different treatments was compared using the Mann-Whitney U test. P values were reported based on a two-sided significance test and the statistical test was interpreted at a 5% level of significance.

3. Results

3.1. Baseline characteristics

The study was conducted from 14 September 2020 to 10 November 2020. A total of 20 participants were included of which data of 19 patients analyzed as one patient was the loss to follow up (B15). The mean age was 35.3±8.9 years and it ranged from 19 to 52 years. All participants were females.

3.2. Comedone grading and comparison

Individual participant data on comedone grade is shown in Table 1. The mean comedone grade was 0.79 for negative control (glycerin) which was significantly less as compared to comedone grade of 2.11 for the positive control (coconut Oil) (Table 2). Similarly, the mean comedone grade for Venusia Max Lotion (PAMA free) was significantly lower as compared to a positive control (1.00 vs. 2.11 respectively, P=.001) (Table 3).

3.3. Adverse Events

There were no adverse events in any of the participants during the study.

Table 1: Comedone grades in individual participants in three groups

Participant code number	Venusia Max Lotion (PAMA free)	Glycerine (Negative Control)	Coconut Oil (Positive Control)
B01	1	1	2
B02	0	0	2
B03	0	0	2
B04	2	1	3
B05	1	0	2
B06	2	1	3
B07	2	2	2
B08	1	0	2
B09	0	0	1
B10	0	0	1
B11	1	2	3
B12	0	0	1
B13	2	2	3
B14	2	1	2
B16	1	1	2
B17	0	0	1
B18	1	2	2
B19	2	1	3
B20	1	1	3

Table 2: Statistical Comparison of meanComedone grades - Positive versus Negative Control (for method validation)

Product	Comedones grade	P value
Coconut oil-Positive Control	2.11±0.74	.001
Glycerine-Negative Control	0.79±0.79	

Table 3: Statistical comparison of meancomedone grades between test product and positive control

Product	Comedones grade	P value
Coconut oil-Positive Control	2.11±0.74	.001
Venusia Max Lotion - PAMA free	1.00±0.82	

4. Discussion

Comedone results from partial or complete obstruction of the pilosebaceous duct and accumulation of sebum. Assessment of comedogenicity is a critical aspect for topical cosmetics, skincare products, and topical medications as well. Acne cosmetica is referred to as the development of comedones caused by the application of cosmetic and skincare products.[7] The use of cosmetic products like moisturizers can cause comedone hyperkeratinization of the follicular epithelium or delayed desquamation of horny cells.[8] Prior to human evaluation, comedogenicity was assessed using the rabbit ear model. The rabbit model was considered more sensitive than the human model. It has been reported that the substances that are weakly comedogenic in the rabbit are probably safe for human use. In 1982, Mills and Kligman proposed a human model for the evaluation of comedogenicity. The degree of follicular hyperkeratosis was assessed by a non-invasive "follicular biopsy" technique, employing a fast-setting cyanoacrylate glue to remove the follicular contents.[7] This method, labelled as cyanoacrylate skin surface stripping (CSSS) or skin surface biopsy or follicular biopsy, is a convenient, low-cost procedure wherein a continuous sheet of stratum corneum and horny follicular casts is collected. Being minimally invasive, it is painless in the majority of the patients and has minimal or no adverse events.[9]

In our study, the comedogenic potential of Venusia Max Lotion (PAMA free) was significantly lower than the positive control (coconut oil). It indicates Venusia Max Lotion (PAMA free) is non-comedogenic. The use of moisturizers provides a significant improvement in skin dryness and comfort to patients with dermatological conditions such as acne vulgaris, acne rosacea.[5,10] Dimethicone and glycerine were the most common ingredients found in moisturizer products. Dimethicone reduces TEWL without a greasy feel and contains both occlusive and emollient properties. It is suitable for acne and sensitive patients as it is non-comedogenic and hypoallergenic. Glycerine is the most effective humectant that increases stratum corneum hydration. Aloe extract

offers anti-inflammatory and skin-soothing properties.[11] Adding moisturizer to the acne treatment provides a more comprehensive management plan that may help in improving cutaneous tolerability and overall improves patient satisfaction.[12] It can be safely used along with cleansers and provides effective relief in acne.[13] The use of non-comedogenic, oil-free moisturizers has been strongly recommended by the Italian guidelines.[14] Constituents in the Venusia Max Lotion (PAMA free) therefore offer benefits of moisturizing and anti-inflammatory effects. As per the results of this study, it is justified that Venusia Max Lotion (PAMA free) is non-comedogenic. In addition, being free from parabens and alcohol, this lotion has a lower risk of irritancy and skin sensitivity. Also, being free of mineral oil, the risk of trapping other pore-clogging ingredients in the skin pores is non-existent.

5. Conclusion

Human evaluation of comedogenicity of moisturizers is an accepted practice. The test product Venusia Max lotion (PAMA free) is found to be non-comedogenic. Clinical use in acne-prone individuals and patients with acne should not be a concern with this product and its use is advisable to improve skin dryness and hydration.

6. Conflict of Interest

The authors declare they have no conflict of interest.

7. Source of F unding

Dr. Reddy's Laboratories Ltd, Hyderabad, India.

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