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Research Article

Real-World Experience to Understand the Usage of Sebamed® Antibacterial Cleansing Foam in the Prevention of Acne

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Abstract

Background: Acne vulgaris is a common condition affecting millions globally, with a high prevalence during puberty. Adult-onset acne, particularly in women, is on the rise. Treatment focuses on sebum control and improving appearance, but adherence poses challenges.

Aim and objective: This study aimed to assess the effectiveness of Sebamed® antibacterial cleansing foam in preventing acne in real-world settings in India.

Methods: This study was a retrospective, multi-centric observational study conducted in 51 Indian healthcare centres. It focused on adult patients with acne vulgaris treated with Sebamed® antibacterial cleansing foam. The study included adult patients of either sex with mild-to-moderate acne or a propensity to develop acne without known allergies or sensitivities to cosmetic products.

Results: In this retrospective analysis of 486 patients, the majority had moderate to severe acne (Grade 2 and Grade 3). Most patients had oily skin (47.9%) and facial acne (92.5%). Sebamed® patients with different grades of acne preferred antibacterial cleansing foam and the median duration of treatment was 2 months. Most patients used the foam twice a day and substantial improvement was observed in 56.4%, with a complete resolution of acne in 3.5%. Most patients experienced better to much better efficacy outcomes in different acne parameters, including oiliness (92.2%), papules (90.7%), pustules (86.3%), nodules (82.1%), open comedones (81.9%) and closed comedones (77.2%). Side effects were observed in 2.5% of patients.

Conclusion: Sebamed® antibacterial cleansing foam shows promising effectiveness and tolerability as a treatment for acne vulgaris. Further research is needed to validate these findings in larger populations.

Keywords: Acne Vulgaris; Antibacterial Foam Cleanser; Efficacy; Safety

Introduction

Acne vulgaris is a multifactorial disorder of the pilosebaceous unit that mainly occurs due to follicular hyperkeratinisation, increased sebum production, bacterial infection and inflammation. It is a common chronic skin disease affecting approximately 117.4 million people globally with a prevalence of almost 95% occurring during puberty [1,2]. However, the incidence of adult-onset acne is increasing with higher rates among women than men [3,4].

The severity of acne has been classified as mild, moderate or severe based on the extent and types of lesions [3]. In addition to physical disfigurement, acne vulgaris has been profoundly linked to significant emotional and psychological distress, which can negatively impact the overall quality of life [5].

The main approach of medical therapy for acne care aims to control sebum secretion, follicular hyperkeratinisation and recurrences and improve appearance. Therefore, topical and oral bactericidal agents that control keratinisation are mostly used for acne treatment. [6] Despite a variety of systemic and topical ointments available for the treatment of acne vulgaris, 10%-15% of patients fail to respond to treatment due to poor adherence [7]. Patients' dissatisfaction with available drug therapy and problems relating to their health were prevalent and associated with noncompliance with medical treatment. For this reason, modern acne treatments have been introduced, which do not only rely on specific drugs but also include add-on products such as moisturisers, cleansers and sunscreens that improve topical drug absorption [6,8].

The liquid skin cleansers are surface-active emulsifiers that remove corneocytes, dirt, sebum and bacteria. There are a variety of acne cleansing agents for acne-prone patients ranging from lipid-free cleansers, syndets, astringents, exfoliants and abrasives [9]. Acne cleansers usually contain alpha hydroxy acids, salicylic acid and benzoyl peroxide [10]. The main adverse effects of most anti-acne therapies are dryness and irritation of the skin, which can present as erythema, scaling and burning sensation [11].

Sebamed® clear face cleaning foam is a soap-free formulation with mild pore-deep cleansing property which removes excess of sebum. This alkali-free cleanser contains mild soap, a new antibacterial agent (Montaline C40), vitamins, lecithin and amino acids, which ensures deep cleaning [12]. However, evidence from clinical trials and real-world studies supporting its use in patients with acne vulgaris in Indian clinical practice is required to establish the efficiency of the product. Therefore, the present study aimed to evaluate the usage of Sebamed® antibacterial cleansing foam in the prevention of acne in real-world Indian settings.

Methodology

Study Design

This was a real-world, retrospective, non-randomized, non-comparative, multi-centric observational study conducted across 51 Indian healthcare centres having medical records of adult patients who had received treatment with Sebamed® antibacterial cleansing foam for acne vulgaris.

Ethics

This study was conducted in accordance with the ethical principles that are consistent with the Declaration of Helsinki, the International Conference on Harmonization of Good Clinical Practices and the applicable legislation on non-interventional studies. The Independent Ethics Committee approved the study protocol before the commencement of the study.

Inclusion and Exclusion Criteria

Patients of either sex with an existing mild-to-moderate level of acne and aged ≥18 years or patients with non-existing acne but prone to develop acne were included. Patients without any known allergy or sensitivity to cosmetic products or fragrances and without any skin allergies or infections, subjects not under any dermatological treatment or infections, were also included in this study. The treating physician had to agree to provide information regarding the participants' treatment. Patients with a known history of allergy or sensitivity to the active ingredients, having any active dermatological skin diseases such as atopic dermatitis, rosacea and psoriasis, patients receiving steroids, antihistamine medications, corticosteroids, flutamide or testosterone, receiving isotretinoin for treating other conditions or patients using contraceptives were excluded. Patients participating in any other similar clinical study or test panel during 3 months before enrolment were excluded from the study. Patients on any other treatment for chronic ailments such as HIV, hepatitis B, hepatitis C and chronic kidney failure or who had planned surgical intervention during the expected study duration and history of any surgical interventions during 3 months before enrolment were also excluded from the study.

Data Collection

Data related to demographic characteristics, clinical characteristics, changes in the number of inflammatory lesions, non-inflammatory lesions, total lesion count, Corneometer evaluation, Sebumeter evaluation, erythema, burning sensation, dryness and scaling, adverse events and safety profiles were collected from patient's medical records.

Endpoints

To evaluate the duration of use of Sebamed® antibacterial facial foam in study patients, medication adherence and safety assessments included monitoring and recording the incidence of all adverse events.

Statistical Analysis

Data were analysed using statistical using SPSS software (version 23). The qualitative data were expressed as number and frequency, while the quantitative data were expressed as mean (Standard Deviation [SD]) or median (range).

Results

A total of 486 patients were enrolled in this retrospective analysis. The mean age of patients was 25.5 years and the proportion of male patients (n=165, 35.2%) was lower than female patients (n=297, 63.3%). The majority of the patients were employed in private service (n=124, 30.0%). Fig. 1 depicts the risk factors observed in the patients, with the consumption of a carbohydrate-rich diet and chocolates being the most common risk factor among them (30.2%). Most patients had oily skin (47.9%), followed by combination skin type (38.8%). The majority of patients had acne predominantly located on their face (92.5%), followed by the back (30.1%) and trunk (21.2%). Grade 2 was the most prevalent (49.5%) among acne vulgaris patients, while grade 3 (40.7%), grade 1 (23.2%) and grade 4 (5.8%) were less frequently observed. Among the alternative soap/facewash options prescribed before Sebamed® antibacterial cleansing foam, the majority of patients (27/165) used Dermadew acne soap, followed by salicylic acid facewash (14/165). The median duration of treatment was 2 months (Supplementary table 1). The majority of participants with acne vulgaris had moderate to severe forms of the condition, with Grade 2 being the most prevalent (49.5%), followed by Grade 3 (40.7%) (Table 1).

The duration of Sebamed® antibacterial cleansing foam use varied among the patients, with 177 patients using it for 1-2 months, 166 patients using it for 1 month, 49 patients using it for 0.5 and 20 patients using it for <0.5 months. The majority of patients (93.0%) used Sebamed® antibacterial cleansing foam twice a day. Among the patients, 466 (95.9%) were using other medications in addition to Sebamed antibacterial cleansing foam. Among these patients, topical retinoids were the most commonly used medication. Substantial improvement of acne after the use of Sebamed® antibacterial foam was observed in most patients (56.4%) and complete resolution of acne was observed in 3.5% of the patients (Table 2). Side effects were observed only in 2.5% of patients.

Supplementary Table 2 reveals the distribution of usage durations and frequencies of Sebamed® antibacterial cleansing foam among male and female patients. The duration of Sebamed® antibacterial cleansing foam use varied among gender, with the majority of male patients (45.8%) using it for 1 month and where the majority of female patients (44.6%) using it for 1-2 months. The majority of male and female patients used Sebamed® antibacterial cleansing foam twice a day (94.4% and 91.5%, respectively).

Table 3 reveals that most patients exhibited better to much better efficacy outcomes in various parameters, including closed comedones (n= 285, 77.2%), open comedones (n= 335, 81.9%), papules (n= 370, 90.7%), pustules (n= 334, 86.3), nodules (n=267, 82.1%) and oiliness (n=355, 92.2%). Physician global evaluation of efficacy and tolerability revealed that most of the patients had good to excellent efficacy (98.1%) and tolerability (98.5%) as depicted in Fig. 2.

Parameters	**Number of Patients (N = 486)***
Age [years], median (range)	[n = 474] 25.5 (11.0-60.0)
Duration of acne [months], median (range)	[n = 361] 2.0 (0.1-60.0)
Sex	[n=469]
Men	165 (35.2)
Women	297 (63.3)
DNW	7 (1.5)
Occupation	[n=414]
Self-employed	114 (27.5)
Government service	28 (6.8)
Private service	124 (30.0)

Any other	43 (10.4)
Student	99 (23.9)
Home-maker	6 (1.4)
Skin characteristics	[n=467]
Oily	224 (47.9)
Dry	62 (13.3)
Mixed	181 (38.8)
Site of acne	[n=438]
Face	405 (92.5)
Back	132 (30.1)
Trunk	93 (21.2)
Any other	11 (2.5)
Stage of acne vulgaris	[n=469]
Grade 1	109 (23.2)
Grade 2	232 (49.5)
Grade 3	191 (40.7)
Grade 4	27 (5.8)
Stage of acne to prefer Sebamed® antibacterial cleansing foam	[n=453]
Grade 1	194 (42.8)
Grade 2	327 (72.2)
Grade 3	181 (40.0)
Grade 4	66 (14.6)
Data presented as n (%), unless otherwise specified. *N=486, unless otherwise specified. DNW, do not want to disclose.	

Table 1: Demographic and clinical characteristics.

Parameters	Number of Patients (N=486)*
Duration of Sebamed® antibacterial cleansing foam [months]	[n=412]
<0.5	20 (4.9)
0.5	49 (11.9)
1	166 (40.3)
1-2	177 (43.0)
Frequency of Sebamed® antibacterial cleansing foam	[n=372]
Once a day	13 (3.5)
Twice a day	346 (93.0)
Thrice a week	13 (3.5)
Other medications prescribed with Sebamed® Antibacterial Cleansing Foam	[n=466]
Topical retinoids	173 (37.1)
Topical benzoyl peroxide	167 (35.8)
Topical antibiotic	153 (32.8)
Topical dapsome	36 (7.7)
Oral isotretinoin	158 (33.9)
Hormonal therapy	12 (2.6)
Oral antibiotic	163 (35.0)
Cost cosmetics procedure	47 (10.1)

Clinical improvement of acne post usage of Sebamed® antibacterial cleansing foam	[n=452]
No improvement	5 (1.1)
Minimal improvement	88 (19.5)
Substantial improvement	255 (56.4)
Significant improvement	86 (19.0)
Complete resolution of acne	16 (3.5)
Worsening	2 (0.4)
Any side effects of Sebamed® antibacterial cleansing foam	12 (2.5)
Data presented as n (%). *N=486, unless otherwise specified.	

Table 2: Management and outcome.

Parameters	Much better	Better	Worse	Much worse	Unchanged
Closed comedones [n=369]	42 (11.4)	243 (65.9)	8 (2.2)	3 (0.8)	73 (19.8)
Open comedones [n=409]	60 (14.7)	275 (67.2)	3 (0.7)	7 (1.7)	64 (15.6)
Papules [n=408]	81 (19.9)	289 (70.8)	6 (1.5)	3 (0.7)	29 (7.1)
Pustules [n=387]	77 (19.9)	257 (66.4)	4 (1.0)	4 (1.0)	45 (11.6)
Nodules, abscesses [n=325]	67 (20.6)	200 (61.5)	4 (1.2)	3 (0.9)	51 (15.7)
Oiliness [n=385]	142 (36.9)	213 (55.3)	1 (0.3)	4 (1.0)	25 (6.5)
Data presented as n (%).					

Table 3: Efficacy of Sebamed® antibacterial cleansing foam.

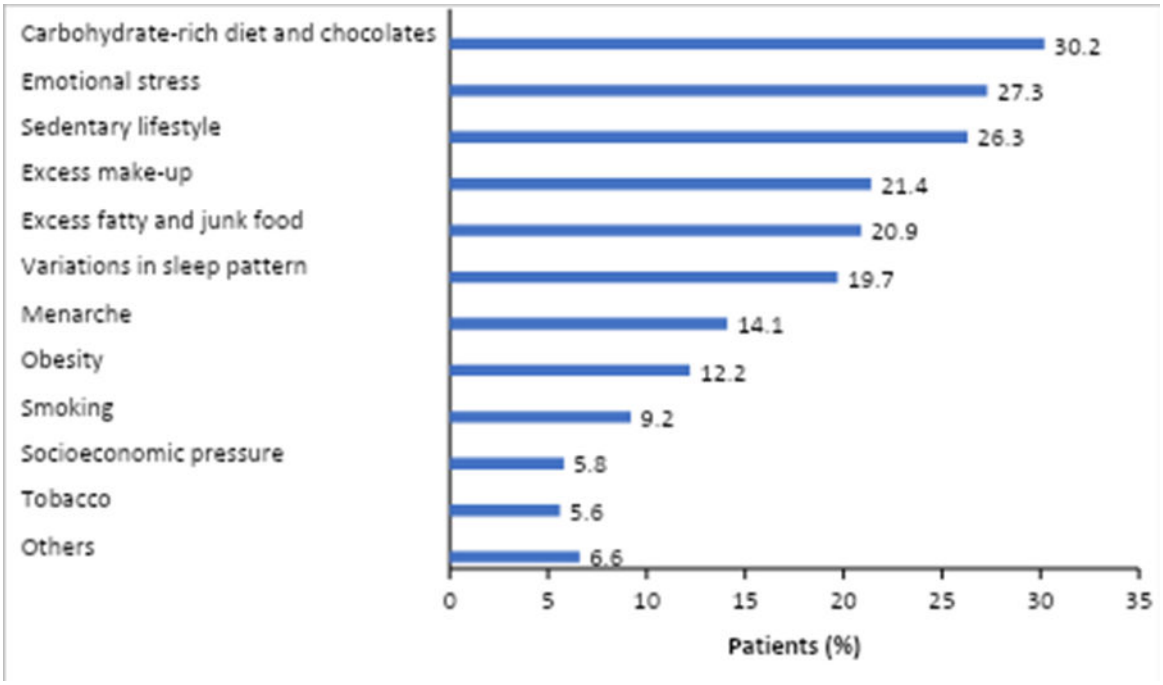

Figure 1: Risk factors. Other risk factors: Drug induced (n=9), 12 (n=1), vitamin B-12 injection (n=2), puberty (n=1), long working hours (n=1), adolescence (n=1), hormonal (n=4), endometriosis (n=3), PCOD (n=2), Travel (n=3). PCOD, polycystic ovarian disease.

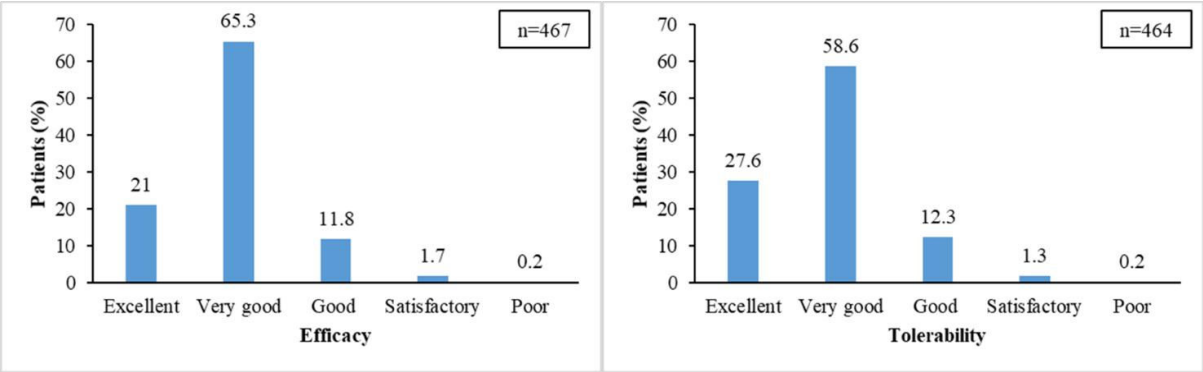

Figure 2: Physician global evaluation of a) efficacy and b) tolerability.

Discussion

Sebamed® antibacterial cleansing foam is a soap-free formulation designed to cleanse pores and reduce excess sebum. This gentle cleanser contains mild soap, an antibacterial agent (Montaline C40), vitamins, lecithin and amino acids for thorough cleansing. Hence, the objective of this study was to assess the effectiveness of Sebamed® antibacterial cleansing foam in preventing acne within real-world settings in India.

The key findings of the present study were i) female predominance, the median age was 25.5 years; ii) common risk factors were carbohydrate-rich diet and chocolate, emotional stress, sedentary lifestyle and excess make-up; iii) most patients had oily skin; iv) common sites of acne were face and back; v) Grade 2 and Grade 3 acne vulgaris were mostly observed; vi) Sebamed® antibacterial foam cleanser was preferred by patients with grade 2 and grade 1 acne vulgaris; vii) substantial improvement after Sebamed® antibacterial cleansing foam use was observed in most patients; viii) side effects observed in 2.5% of patients; ix) improvement was observed in closed comedones, open comedones, papules, pustules, nodules and oiliness; x) physician global evaluation revealed very good efficacy and tolerability in most patients.

In the present study, 63.3% of females presented with acne vulgaris. Female predominance in patients with acne vulgaris is also reported in previous studies. [13-16] Women in their third and fourth decades presented with acne [17].

The current study identified risk factors like a carbohydrate-rich diet and chocolate, emotional stress, a sedentary lifestyle, excess make-up and variations in sleep patterns in patients with acne vulgaris. High sugar-content meals, such as white bread, white rice and chocolate, promote insulin release, which subsequently stimulates the Akt signalling pathway, which in turn disables Forkhead box protein O1 (FoxO1). FoxO1 inactivation, in consequently, causes gene transcription and induces keratinocyte proliferation in the pilosebaceous unit [18]. Another study [19] revealed that intake of high carbohydrates, chocolate and dairy was associated with acne presentation. Similarly, Shah N, et al., found that individuals with acne vulgaris consumed oily and high glycemic foods, as well as experienced chronic stress [13]. Another study revealed that stress, fatty food consumption and makeup aggravate acne [20].

The current study revealed that the highest occurrence of acne was observed on the face (92.5%), followed by the back (30.1%) and trunk (21.2%) of the patients. On parallel lines with the present study, Shah N, found that most patients had facial acne on the cheeks (85.0%) and at mandibular area (32.8%), followed by truncal acne (23.8%). In harmony with previously mentioned studies, Adityan B, et al., face (65.4%), chest (20.1%) and back (28.2%) were the common sites of acne [21].

In this study, Grade 2 acne vulgaris was prevalent, followed by Grade 3 acne vulgaris. On the contrary, another study had the majority of patients with Grade 1 acne vulgaris followed by Grade 2 acne vulgaris [21]. While in a study conducted by Shah N, et al., Grade 2 acne vulgaris was prominent (72.8%) [13].

Conventional treatments for acne have shown unsatisfactory results due to non-compliance [22]. Therefore, modern acne treatments have expanded to include additional products like moisturisers, cleansers and sunscreens to improve the absorption of topical medications. Cleansing is a crucial step in removing dirt, dead cells and accumulated skin products [22,23]. Effective

cleansers function as emulsifiers, reducing surface tension and aiding in the removal of dirt, oil, microorganisms and exfoliated skin cells. Acne treatment often involves the use of various types of cleansers, such as lipid-free cleansers, synthetic detergents (syndets), astringents, exfoliants or mild abrasives [22]. However, it is important to select a cleanser that does not disrupt the skin's natural protective components or deplete essential lipids, preserving the skin's barrier function and preventing excessive water loss. Traditional components of cleansers are surfactants, moisturisers, water, lather enhancers, fragrance, fillers and preservatives [22]. Sebamed® antibacterial cleansing foam contains a novel antibacterial agent (Montaline C40).

In this study, most patients used Sebamed® antibacterial cleansing foam twice daily, resulting in a substantial to significant improvement in 75.4% of patients. Similarly, face rinsing with cleansers twice a day has been shown to reduce both inflammatory and non-inflammatory breakouts [24,25]. After using Sebamed® antibacterial cleansing foam, a notable improvement in closed comedones, open comedones, papules, pustules, nodules and oiliness was observed. Likewise, patients who used foaming cleansers twice daily experienced a decrease in a number of open comedones and non-inflammatory lesions ($p=0.03$) [26]. Another study reported a significant improvement in acne after 2 weeks of cleanser use [27]. No existing literature has reported side effects with the use of foaming cleanser with mild soap.

Conclusion

Sebamed® antibacterial cleansing foam is an effective treatment option for acne vulgaris, yielding positive outcomes and demonstrating good tolerability. However, further research is warranted to validate these results and explore its efficacy in larger population. Overall, Sebamed® antibacterial cleansing foam holds promise as a valuable tool in managing acne vulgaris in real-world clinical settings.

Conflicts of Interest

The authors declare no conflict of interest in this paper.

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None

Authors' Contributions

All authors contributed to conceptualization, treatment execution, manuscript writing and final approval.

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