International Journal of Research in Dermatology
Gupta S et al. Int J Res Dermatol. 2023 Nov;9(6):353-361
http://www.ijord.com

DOI: https://dx.doi.org/10.18203/issn.2455-4529.IntJResDermatol20233179

Original Research Article

Cetyl alcohol, stearyl alcohol and colloidal oatmeal-based gentle skin cleanser in management of dry and sensitive skin: a cross-sectional study

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Received: 29 July 2023
Revised: 02 September 2023
Accepted: 07 September 2023

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ABSTRACT

Background: Effective skin cleansing is vital for maintaining skin health and appearance. An ideal skin cleaner retains moisture, removes oils, sweat, and dirt without causing irritation or dehydration. This study was designed to evaluate the efficacy, safety, tolerability and usage trends of a gentle skin cleanser containing cetyl alcohol, stearyl alcohol and colloidal oatmeal for individuals having dry and sensitive skin.
Methods: We conducted a retrospective review at 102 centres, focusing on individuals aged 18 to 65 years with atopic dermatitis and dry skin conditions who required the use of gentle skin cleanser. Total 568 cases were taken; 488 cases of dry and sensitive skin were further analysed over a 2-week study period.
Results: Gentle skin cleanser exhibited significant reduction ($p<0.0001$) in skin dryness, itchiness and irritation by 4.42±1.92 (63.38%), 4.03±2.71 (49.38%) and 4.44±2.07 (65.58%) respectively in participants with dry skin and by 4.25±1.48 (58.49%), 3.26±3.22 (18.02%) and 4.42±1.56 (63.23%) in participants with sensitive skin after its regular usage. Participants provided positive feedback and expressed overall satisfaction with the study product.
Conclusions: Skin cleanser was efficacious and well-tolerable in participants in providing moisturizing, soothing, exfoliating, and antioxidant effects making it a preferred primary choice for managing dry and sensitive skin. The cleanser effectively cleansed excess oil, dirt, dead cells, microorganisms, and sweat providing a gentle and mild experience, in daily skin care.

Keywords: Dry skin, Sensitive skin, Moisturizing, Itchiness, Pollutant, Irritation

INTRODUCTION

Dry skin or xerosis is a condition characterized by frequent pruritus, loss of skin suppleness, and rough, scaly, or flaky skin. Similarly, sensitive skin is a condition marked by stinging, burning and itching sensations.[1,2] It is estimated that 9.4% of the world's population suffers from sensitive skin and various related disorders. The most typical symptoms of sensitive skin include skin dryness, burning, tingling, pungency, itchiness, skin redness, acne vulgaris, and other skin inflammation.[3,4] Environmental causes for dry and sensitive skin include conditions like ichthyosis vulgaris and atopic dermatitis as well as frequent washing, showering, and exposure to low air humidity. Seasonal and ageing variables can have a major impact on the hydration and suppleness of the skin. As a result, dry sensitive skin is more prevalent in the winter when the air is less humid. All these skin problems can be diminished by use of good cleanser.[5]

Skin cleansers are surface-active substances which work by lowering the surface tension on the skin and removing impurities like dirt, sebum, oil from cosmetic products, microorganisms, and exfoliated corneum cells in an emulsified form.[6] Over a few thousand years, the art of cleansing has greatly advanced, going from just scraping the skin to today's exercise in relaxation and improvement of the health and beauty of the skin. An ideal skin cleanser should accomplish all of this without causing the skin any harm or irritation and maintaining the skin's surface moist and remove skin lipids, sweat, and surface grime without irritating or drying out the skin.[7,8]

Skin cleanser contains active ingredients like glycerine vitamin E, colloidal oatmeal, and castoryl maleate. Glycerin works as a humectant which moisturises the skin, lessen dryness, and revitalise the outermost layer of the skin.[9-11] Colloidal oatmeal provides a multi-therapy approach benefiting dry and compromised skin and alleviating skin irritation and inflammation.[12] Topical vitamin E is another ingredient which has antioxidant and free radical scavenging properties.[13] High grade fatty alcohols including cetyl alcohol and stearyl alcohol are used as emollients. They have a tendency to soften and smoothen skin, which helps to lessen skin dryness, roughness and give a soft feeling when applied to the skin.[14] Castoryl maleate is a lipid analogue which provides superior moisturization, reduced irritation when applied on skin.[15]

So, a combination of this along with other mentioned ingredients works as a remedy for dry and sensitive skin and gives smooth shiny and healthy skin. This study was a population-based study conducted in outpatient settings in India to evaluate the real-world assessment of best clinical practices for managing patients with dry skin and sensitive skin. The study aimed to assess the clinical impact and determine the therapeutic efficacy of gentle skin cleanser.

METHODS

Study design and patient population

This study was a post-approval, cross-sectional, single-arm, observational, multicentre clinical study to evaluate the clinical effects, trends of usage, and safety of a skin cleanser formulated with cetyl alcohol, stearyl alcohol, glycerin, vitamin E, and colloidal oatmeal. The study was conducted for the duration of two weeks in the month of June 2023 including patients who visited dermatologic outpatient clinics in 102 different locations across India focusing on individuals with dry and sensitive skin. The main centre for recruitment was Dr Hemendra Shah's clinic, Ahmedabad, Gujarat.

The study included 568 participants aged 18 to 65 years with dry sensitive skin requiring addition of skin cleanser in their daily routine. The study analysed case records of total 568 participants who completed the 2 weeks of therapy. Further analysis was done for 412 (72.53%) and 76 (13.38%) intent-to-treat (ITT) population having complaints of dry skin and sensitive skin respectively. No participants were lost to follow up in this study. Patients with allergic skin diseases other than acne were excluded from the study.

Demographic information, diagnosis, baseline skin dryness, co-morbidities, patient global assessment (PGA) score, and duration of treatment completed for each patient was collected. A post-hoc analysis was conducted on this subgroup to explore specific aspects and variables of interest. The study involved two evaluation visits. During visit 1, patients were enrolled and received the study cleanser, and visit 2, which took place at the completion of a 2-week treatment period for patient assessment.

The study was conducted in accordance with the declaration of Helsinki (Brazil, October 2013), good clinical practices for clinical research in India 2005, new drugs and clinical trials rules 2019, ICH GCP E6 (R2) guidance on good clinical practice, and with ICMR's national ethical guidelines for biomedical and health research involving human participants, 2017. Approval from independent ethics committee was also obtained for each centre before the commencement of the study. The study was registered with the clinical trials registry of India (CTRI/2023/06/053708) on 09 June 2023.

Skin cleanser

Gentle skin cleanser contains glycerin, cetyl alcohol, stearyl alcohol, castoryl maleate, colloidal oatmeal, butylene glycol, xanthan gum, phenoxyethanol (and) ethylhexylglycerin, sodium lauryl sulfate, polysorbate 20, phenylethyl alcohol, vitamin E acetate, and triethanolamine. The cleanser was used topically for the treatment of dry and sensitive skin conditions and was applied two or three times daily or as prescribed by the medical professional (Table 1).

Table 1: Study drug.

Parameter(s)	Treatment
Product name	**Ahaglow gentle skin cleanser**
	Ingredients list: Purified water, glycerin, cetyl alcohol, castoryl maleate, colloidal oatmeal, butylene glycol, xanthan gum, phenoxyethanol (and) ethylhexylglycerin, sodium lauryl sulfate, polysorbate 20, stearyl alcohol, phenylethyl alcohol, vitamin E acetate and triethanolamine
Dosage form	Lotion
Dosage	Apply two to three times daily or as prescribe by physician
Route of administration	Topical
Manufacturer	Torrent pharmaceuticals ltd

Procedure

A post-hoc analysis was conducted on patients having dry and sensitive skin to explore specific aspects and variables of interest. The study evaluated the following objectives: (A) the clinical impact, utilization, and safety of an oatmeal based gentle skin cleanser in various facial skin conditions, including skin hygiene, acne, aging, and post-procedure care. (B) analysed the utilization patterns of the cleanser and examined its effects on different skin issues. (C) assessed patient outcomes and ensured patient safety after the completion of a 2-week treatment period. The study consisted of two visits. At visit 1, referred to as the screening visit, skin cleanser was prescribed and were followed up for 2 weeks. Before conducting any procedures or assessments, patients were provided with a comprehensive explanation of the study's nature and potential risks. During this visit, inclusion/exclusion criteria were evaluated, and various aspects such as demographics, physical examination (including age, height, weight, body mass index), medical and surgical history, smoking and alcohol intake, current treatment history, and assessment of concomitant medication were recorded. The outcome assessment, including patient global assessment (PGA) and safety evaluation, was conducted at visit 2 after a duration of 2 weeks. PGA was also conducted to evaluate improvement at visit 2.

Vital signs assessments were performed according to routine clinical practice and the discretion of the treating physician. Any notable findings during the Screening visit were also documented in the medical and surgical history records. As the study was conducted in a real-life setting, the study medication was prescribed by the investigator, and patients obtained the drug from pharmacy stores. Compliance was assessed using case record sheets, and source data was reviewed to ensure compliance. Participants were considered to have completed the study if they adhered to the 2-week treatment period, which was recorded in the case report form.

During the entire study duration, close monitoring and documentation of adverse events (AEs) and treatment-emergent adverse events (TEAEs) was done in order to evaluate the safety and tolerability of the intervention.

Statistical methods

Patient demographic details, including modifiable and non-modifiable risk factors, comorbidities, were analysed using descriptive statistics. Qualitative variables were reported using frequencies and percentages. Quantitative variables were summarized using means, medians, standard deviations, minimum and maximum values, and 95% confidence intervals. To assess the significance of continuous and categorical variables, the student's paired t-test was utilized, with a $p<0.05$ considered clinically significant. The two-tailed test was employed for these analyses. Continuous variables were presented as mean ± standard deviation, while categorical variables were presented as numbers and proportions of patients. All statistical analyses were performed using SPSS software version 29.0.1.0 (171).

RESULTS

A total of 568 participants were involved in the study who underwent one follow-up assessment to evaluate safety and effectiveness. The analysis specifically focused on a subset of 412 (72.53%) participants with dry skin and 76 (13.38%) participants with sensitive skin. Out of 568 participants, 199 (35.00%) were males, while 369 (65.00%) were females. The delta (Δ) age, weight, and height of the study participants were 28.82 years±8.64 (Mean SD), 62.85±11.26 kg (Mean SD), and 160cm±15.37 (Mean SD), respectively (Table 2). Detailed evaluation of underlying medical conditions such as allergy, rhinitis, psoriasis, keratosis pilaris, rosacea, folliculitis, and types of skin were also assessed and expressed in Table 3. Throughout the study, a total of 568 participants were included in the Per Protocol (PP) dataset for further assessments, including the FAS (Full analysis set) for parameters related to dryness, itchiness, and irritation. Following a 2-week duration of product usage, a statistically significant reduction ($p<0.0001$) was observed in skin dryness (62.28%), itchiness (46.07%), and irritation (64.29%) compared to the baseline measurement taken on day 00 (Per protocol population). Evaluating the patient global assessment, it was noted that 253 patients (45%) reported excellent results, 274 patients (48.32%) reported good results, 39 patients

(6.87%) reported fair results, and only 1 patient reported poor results.

Out of the total participants, 433 (41.27%) demonstrated adequate adherence to the usage of gentle skin cleanser. Additionally, 418 participants (39.84%) exhibited highly adequate adherence to the cleanser. However, 129 participants (12.29%) did not use gentle skin cleanser adequately. Following a 2-week usage of the product during the winter season, a statistically significant reduction was observed in skin dryness (62.08%), itchiness (58.77%), and irritation (65.64%) compared to the baseline measurement taken on day 00, with a $p<0.0001$. Analysing the patient global assessment, it was determined that 185 patients (45.79%) reported excellent results, 187 patients (46.28%) reported good results, and 32 patients (7.92%) scored fair results. Notably, a significant improvement of 100% was observed, as all patients achieved scores above the PGA score. Similarly, after a 2-week period of using the product during the Monsoon season, a statistically significant reduction was observed in skin dryness (55.16%), itchiness (53.37%), and irritation (51.49%) compared to the baseline measurement taken on day 00, with a $p<0.0001$. Evaluating the patient global assessment, it was found that 6 patients (33%) reported excellent results, 9 patients (61.11%) reported good results, and 1 patient (6%) scored poor results.

It has been observed that during the summer season, after 2 weeks of usage of the product, there was a statistically significant reduction ($p<0.0001$) observed in skin dryness (64.07%), itchiness (0.53%) and irritation (61.95%) from baseline i.e., day 00. Based on the patient global assessment, it was found that there were 51 patients (41.80%) stated excellent results, 66 (54.09%) stated good results, 5 (4.09%) patient scored Fair results. During the Spring season, a statistically significant reduction ($p<0.0001$) was observed in skin dryness (67.70%), itchiness (67.20%), and irritation (59.92%) after 2 weeks of using the product, compared to the baseline measurement taken on day 00. According to the patient global assessment, 4 patients (80%) reported excellent results, while 1 patient (20%) reported good results.

For patients with dry skin, there was a statistically significant reduction ($p<0.0001$) shown in skin dryness (63.38%), itchiness (49.38%) and irritation (65.58%) from baseline i.e., day 00 to after 2 weeks of usage of the test product (Table 4). Similarly, statistically significant reduction ($p<0.0001$) was shown in skin dryness (58.49%), itchiness (18.02%) and irritation (63.23%) from baseline i.e., day 00 to after 2 weeks of usage of the test product in patients suffering from sensitive skin (Table 5).

Based on PGA score, it was concluded that overall, a very good mildness (n=255) (45.21%), soothiness (n=245) (43.13%), cleansing (n=226) (40.07%) and Pollutants removal (n=200) (35.5%) effect was present in the subjects who had used the skin cleanser (Table 6). 100% of patients had improvement in their skin conditions. Additionally, when the product was used twice daily, 425 participants showed a statistically significant reduction ($p<0.0001$) in dryness (60.54%), itchiness (38.32%) and irritation (62.47%), as per Table 7, when compared from baseline visit to 2 weeks follow-up.

In the winter season, out of the 404 subjects, 75% (303) applied gentle skin cleanser twice a day (BD frequency), 6.68% (27) applied it once a day (OD frequency), 15.84% (64) applied it three times a day (TD frequency), 1.49% (6) applied it four times a day (QD frequency), and the remaining 0.99% (4) had a customized frequency of application. Similarly, in the summer season, out of the 122 subjects, 75.41% (92) applied gentle skin cleanser twice a day (BD frequency), 4.10% (5) applied it once a day (OD frequency), 19.67% (24) applied it three times a day (TD frequency), and 1.64% (2) applied it four times a day (QD frequency). For the 16 subjects in the monsoon season, 56.25% (9) applied gentle skin cleanser twice a day (BD frequency), 6.25% (1) applied it once a day (OD frequency), 31.25% (5) applied it three times a day (TD frequency), and 6.25% (1) applied it four times a day (QD frequency).Lastly, out of the 5 subjects in the spring season, 60% (3) applied gentle skin cleanser twice a day (BD frequency), 20% (1) applied it three times a day (TD frequency), and 20% (1) applied it four times a day (QD frequency).

Among the subjects using gentle skin cleanser, different frequencies of application were evaluated. In the group applying the cleanser once a day (OD), 52.94% reported excellent mildness results, 29.41% had very good results, 14.71% had good results, and only 2.94% had poor results. For those applying the cleanser twice a day (BD), 0.31% reported excellent mildness results, 0.46% had very good results, 0.23% had good results, and only 0.004% had poor results out of a total of 425 subjects. Among the subjects applying the cleanser three times a day (TD), 0.51% reported excellent mildness results, 0.41% had very good results, and 0.08% had good results out of a total of 95 subjects. In the group applying the cleanser four times a day (QD), 70% reported excellent mildness results, 20% had very good results, and 10% had good results out of a total of 10 subjects.

Among the 404 subjects in the Winter season, 0.34% experienced an excellent cleaning effect, followed by 0.37% with a very good effect, 0.26% with a good effect, and only 0.01% had a fair cleansing effect. In the summer season, out of the 122 subjects, 26.23% reported an excellent cleaning effect, 49.18% experienced a very good effect, 26.23% had a good effect, and only 1.64% had a fair cleansing effect. For the 16 subjects in the Monsoon season, 0.25 percentage had an excellent cleaning effect, 0.31 percentage experienced a very good effect, 0.38 percentage reported a good effect, and only

0.06 percentage had a fair cleansing effect. Among the 5 subjects in the spring season, 20 percentage experienced an excellent cleaning effect, 20% had a very good effect, 60 percentage reported a good effect, and only 20 percentage had a fair cleansing effect.

In terms of correlation between pollutant removal effect and cleansing effect of the product, 20.9% exhibited both an excellent cleansing effect and pollutant removal effect, followed by 20.8% who showed both a very good cleansing effect and pollutant removal effect. Additionally, 13.2% of subjects demonstrated both a good cleansing effect and pollutant removal effect, while only 0.7% exhibited both a fair cleansing effect and pollutant removal effect (Table 8).

Based on the data, it is evident that the majority of subjects experienced excellent to very good effects using gentle skin cleanser. The cleanser effectively eliminates pollutants from the skin and provides a gentle and soothing effect, promoting mildness and comfort by removing dirt, oil, pollutants, and the dust. Since a majority of subjects four hundred and twenty-five (425) applied the cleanser twice a day, they experienced both very good to excellent mildness as well as the cleansing effects.

In terms of safety, none of the subjects experienced any AE/TEAE at the end of study period. The product was found safe and well tolerable on the study population. Overall, the results demonstrated that cleanser is safe and effective for use in patients with dry and the sensitive skin.

Table 2: Demographic distribution of study subjects.

Variables	Demographic distribution		
	Male, (n=199), (35.00%)	**Female, (n=369), (65%)**	**Overall, (n=568)**
	Mean (SD)	**Mean (SD)**	**Mean (SD)**
Age (In years)	28.83 (8.64)	28.99 (8.68)	28.82 (8.64)
Height (cm)	160.08 (15.37)	160.05 (15.60)	160.07 (15.38)
Weight (kg)	62.85 (11.26)	62.93 (11.40)	62.85 (11.27)

Table 3: Details of underlying skin condition and types of skin.

Parameters		Count	Percentage (%)
Underlying skin conditions	Allergic rhinitis	21	4.2
	Allergic rhinitis, itchy skin	9	1.8
	Allergic rhinitis, psoriasis	2	0.4
	Allergic rhinitis, folliculitis	2	0.4
	Folliculitis	5	1
	Itchy skin	177	35.7
	Itchy skin, folliculitis	2	0.4
	Itchy skin, psoriasis	1	0.2
	Keratosis pilaris	18	3.6
	Keratosis pilaris, folliculitis	3	0.6
	Keratosis pilaris, itchy skin	48	9.7
	Keratosis pilaris, rosacea	1	0.2
	Keratosis pilaris, psoriasis	12	2.4
	Psoriasis	16	3.2
	Psoriasis, itchy skin	1	0.2
	Rosacea	44	8.9
	Rosacea, allergic rhinitis	1	0.2
	Rosacea, folliculitis	3	0.6
	Rosacea, itchy skin	78	15.7
	Rosacea, psoriasis	23	4.6
Type of skin	Dry	404	71.1
	Dry, mix type	2	0.4
	Dry, sensitive	2	0.4
	Mix type	82	14.4
	Mix type, sensitive	1	0.2
	Oily, dry	4	0.7
	Oily, mix type, sensitive	1	0.2
	Sensitive	72	12.7

Table 4: Descriptive statistics for participants with dry skin.

Statistics	Dryness				Itchiness				Irritation			
	Visit 1 Baseline	Visit 2 2 weeks	CFB	%CFB	Visit 1 Baseline	Visit 2 2 weeks	CFB	%CFB	Visit 1 Baseline	Visit 2 2 weeks	CFB	%CFB
N	412	412	412	412	412	412	412	412	412	412	412	412
Minimum	3.00	0.00	-8.00	-100.00	1.00	0.00	-8.00	-100.00	0.00	0.00	-9.00	-100
Maximum	9.00	8.00	0.00	0.00	9.00	9.00	8.00	800.00	9.00	8.00	0.00	0.00
Mean	6.86	2.43	-4.42	-63.38	6.58	2.55	-4.03	-49.38	6.72	2.28	-4.44	-65.58
Std. error	0.06	0.07	0.09	1.19	0.09	0.10	0.13	4.79	0.08	0.08	0.10	1.31
Std. deviation	1.30	1.51	1.92	24.17	1.74	1.94	2.71	97.13	1.70	1.70	2.07	26.47
P value	<0.0001				<0.0001				<0.0001			

Table 5: Descriptive statistics for participants with sensitive skin.

Statistics	Dryness				Itchiness				Irritation			
	Visit 1 Baseline	Visit 2 2 weeks	CFB	%CFB	Visit 1 Baseline	Visit 2 2 weeks	CFB	%CFB	Visit 1 Baseline	Visit 2 2 weeks	CFB	%CFB
N	76	76	76	76	76	76	76	76	76	76	76	76
Minimum	3.00	0.00	-7.00	-100.00	1.00	0.00	-7.00	-100.00	2.00	0.00	-8.00	-100.00
Maximum	9.00	8.00	-1.00	-11.11	9.00	9.00	8.00	800.00	9.00	9.00	0.00	0.00
Mean	7.43	3.18	-4.25	-58.49	6.89	3.63	-3.26	-18.02	7.14	2.72	-4.42	-63.23
Std. error	0.15	0.20	0.17	2.29	0.24	0.25	0.37	16.90	0.17	0.20	0.18	2.35
Std. deviation	1.33	1.79	1.48	19.97	2.13	2.20	3.22	147.35	1.49	1.71	1.56	20.51
P value	<0.0001				<0.0001				<0.0001			

Table 6: PGA score for use of gentle skin cleanser.

Variables	Mildness		Soothiness		Cleansing		Pollutant removal	
	N	%	N	%	N	%	N	%
Excellent	184	32.62	230	40.49	181	32.09	160	28.46
Very good	255	45.21	245	43.13	226	40.07	200	35.58
Good	122	21.63	91	16.02	147	26.06	152	27.04
Fair	3	0.53	2	0.35	10	1.77	50	8.89
Total	564	100	568	100	564	100	562	100

Table 7: Descriptive statistics for participants having twice daily usage of study product.

Statistics	Dryness				Itchiness				Irritation			
	Visit 1 Baseline	Visit 2 2 weeks	CFB	%CFB	Visit 1 Baseline	Visit 2 2 weeks	CFB	%CFB	Visit 1 Baseline	Visit 2 2 weeks	CFB	%CFB
N	425	425	425	425	425	425	425	425	425	425	425	425
Minimum	3.00	0.00	-9.00	-100.00	0.00	0.00	-9.00	-100.00	0.00	0.00	-9.00	-100.00
Maximum	9.00	8.00	0.00	0.00	9.00	9.00	8.00	800.00	9.00	9.00	0.00	0.00
Mean	6.91	2.68	-4.22	-60.54	6.52	2.91	-3.63	-38.32	6.74	2.52	-4.26	-62.47
Std. error	0.07	0.07	0.08	0.99	0.08	0.08	0.12	4.25	0.07	0.07	0.09	1.10
Std. deviation	1.36	1.59	1.86	23.92	1.94	2.07	2.90	115.07	1.76	1.73	2.01	26.27
P value	<0.0001				<0.0001				<0.0001			

Table 8: Correlation between pollutants removal effect with cleansing effect.

Variables			Cleansing effect				Total
			Excellent	Fair	Good	Very good	
Pollutants removal	Excellent	N	117	0	5	57	179
		%	20.9	0	0.9	10.2	32
	Fair	N	0	4	4	1	9
		%	0	0.7	0.7	0.2	1.6
	Good	N	2	45	74	25	146
		%	0.4	8.1	13.2	4.5	26.1
	Very good	N	41	1	67	116	225
		%	7.3	0.2	12	20.8	40.3
Total		N	160	50	150	199	559
		%	28.6	8.9	26.8	35.6	100

DISCUSSION

There are continuing investigations looking for a better molecule to cure the dry skin or sensitive skin concern. Numerous studies have indicated that roughly 50% of people claim to have dry or sensitive skin, which has generated a great deal of attention.[16] To establish the above goal, we conducted a study to assess, clinical impact, utilization and safety of cetyl alcohol, stearyl alcohol and oatmeal based gentle skin cleanser in facial dry and sensitive skin conditions. A subgroup analysis was conducted on patients having dry and sensitive skin to derive further insights on these skin types. The results of primary endpoints analysis stated that the investigational product yielded beneficial results and exhibited efficacy in the reduction of skin dryness, itchiness and irritation.

Harsh soaps that contain detergents pull away the skin's natural emollients, aggravating and drying the skin out. Hence, addition of skin cleansers in our daily skincare routine plays an essential role in treating dry skin conditions.[13] Moreover, cleansers exhibit the range of effects including removal of sebum, dirt, dead cells, and microorganisms from skin and providing skin moisturizing effect to the skin. Gentle skin cleanser contains various beneficial ingredients. Active ingredients present in cleanser are glycerin, vitamin E, colloidal oatmeal, and castoryl maleate. Glycerin, a moisturizing agent, works by attracting water from deeper layers of the skin to the outer layer, and acts as a natural endogenous humectant.[1717]

The role of endogenous glycerin in hydration of stratum corneum in humans was expressed by Choi et al[18]. Breternitz et al conducted a placebo-controlled, double-blind, randomized prospective study on eczematous skin in atopic dermatitis which showed the improvement in skin hydration with glycerin use.[19] Similar results were also evident in our study, showing reduced skin dryness, post test product usage. Vitamin E acetate, an antioxidant, safeguards the skin against harmful effects of solar radiation by scavenging free radicals and reducing potential damage.[20]

Various studies have reflected role of topical vitamin E in improvement of various skin parameters like acute and chronic dermatitis, erythema, edema, skin hydration, roughness, wrinkling, and sebum production.[21-24] Colloidal oatmeal strengthens skin barrier and provides benefits for dry and compromised skin and alleviate skin irritation and inflammation.[25] Results of our study are supported by this statement. Based on the results of the clinical study, gentle skin cleanser has shown statistically significant improvements ($p<0.0001$) in reducing skin dryness by 62.28%, itchiness by 46.07%, and redness by 64.29% after 2 weeks, compared to the initial measurements taken on Day 00. The patient global assessment provided positive feedback for the product. Kim et al also proved the same where the results showed the visible improvement observed in the control group who used only a gentle cleanser.[26] Several research studies have proven efficacy of oatmeal as a treatment for dry, itchy, and irritated skin dermatoses.[27-30] Since the FDA approved colloidal oatmeal's usage as a skin protector in 2003, it is now frequently used to treat skin rashes, erythema, burns, itching, and eczema.[25,30,31] Our test product Ahaglow Gentle Skin Cleanser significantly highlighted its remarkable benefits for patients with various conditions of dry and sensitive skin.

The findings from this study aligns with previous research, supporting the rationality and advantages of employing gentle cleansing therapy in daily routine. In addition, gentle skin cleanser possesses cleansing properties that effectively eliminate pollutants from the skin. It imparts a gentle and soothing effect, delivering mildness and comfort to the skin by removing dirt, oil, pollutants and dust.

This study has some limitations that should be acknowledged. One major challenge encountered by treating physician was to assess the patient adherence to the study product and shorter study duration. Additionally, due to observational and non-comparative study design the findings are not supported by histological evaluation or objective/quantitative assessments.

In summary, gentle skin cleanser offers notable benefits for individuals seeking relief from dryness, itchiness, and irritation. Its mild formulation and ability to maintain

proper hydration of the outermost layer of the skin, known as the stratum corneum, make it an excellent choice for individuals with dry and sensitive skin.

CONCLUSION

This study adds valuable evidence to existing studies related to skin cleansers containing cetyl alcohol, stearyl alcohol, colloidal oatmeal, castoryl maleate, and vitamin E. Our product was effective and well tolerated in targeted population for its intended use. The cleanser not only efficiently cleansed excess oil, dirt, dead cells, microorganisms, sweat, and dust from the skin, but it also provides a soothing and gentle cleansing experience. This gentle skin cleanser is effective in population with dry and sensitive skin type.

ACKNOWLEDGEMENTS

The authors would like to thanks to Dr Nayan Patel (MBBS) and Ms. Maheshvari Patel (PhD Scholar, Pharmacology) for their valuable support in the preparation of this manuscript. Additionally, we sincerely thank CASO-DSS study Investigator(s) panel for participation of the study as clinical researcher and all the patients who participated in this study for their contribution. *CASO study investigator(s) Panel-Sogani M. (Surat), Kaur J. (Vapi), Shah S. (Vapi), Khandelwal A. (Mhow), Adulkar S. (Nagpur), Sirsikar A. (Kalyan), Nijawan S. (Jaipur), Sampatkumar R. (Kolhapur), Pawar S. (Akluj), Kadam A. (Satara), Matsawar J. (Aurangabad), Borole M. (Jalgaon), Mahajan R. (Vadodara), Chalissery J. (Ernakulam), Bhatt N. (Kanhangad), Theruvath S. (Alappuzha), Joseph A. (Kottayam), Joseph J. (Pala), Reddy S. (Hyderabad), T. N. (Karimnagar), Betkerur J. (Mysore), Odugodra S. (Hubli), Gurumoorthi R. (Ooty), Nanjappasetty G. (Salem), Sahu S. (Jhansi), Gandhi N. (New Delhi), Gupta N. (Panchkula), Prashar A. (Chandigarh), Chawla S. (Agra), Sharma S. (Kanpur), Biswas S. (Kolkata), Butt A. (Cooch Behar), Poddar S. (Asansol), Mishra C. (Bhubaneswar), Jha S. (Patna), Mohanty M. (Berhampur), Krishnakanth M. (Chennai), Ms. Gowtham (Salem), Verma A. (Hajipur), Soni S. (Bhopal), Mohod S. (Amravati), Gulane S. (Yavatmal), Gharghe S. (Satara), Harnalikar M. (Nanded), Salve G. (Aurangabad), Survase A. (Alephata), Batra A. (Jodhpur), Shah R. (Vadodara), Singh G. (Ghaziabad), Jain R. (Dimapur).

Funding: Funding sources by Torrent Pharmaceuticals Ltd, Ahmedabad, India.
Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee CTRI Registration: Yes, CTRI/ 2023/06/053708

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Cite this article as: Gupta S, Shah HB, Bhardwaj P, Holani A, Singh C, Yadav S et al. Cetyl alcohol, stearyl alcohol and colloidal oatmeal-based gentle skin cleanser in management of dry and sensitive skin: a cross-sectional study. Int J Res Dermatol 2023;9:353-61.