



Research Article

A SINGLE CENTRE OPEN LABEL POST MARKETING SURVEILLANCE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF ROOP MANTRA CUCUMBER AYURVEDIC MEDICINAL FACE WASH

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ABSTRACT

The objective of the study was to assess the safety and efficacy of Roop Mantra Cucumber Ayurvedic Medicinal Face Wash in subjects with acne, facial scars, pimples, blemishes, dull skin and dry skin. **Methods:** This was a single-center, open-label, non-randomized post-marketing surveillance study with 120 subjects. Subjects were selected on the basis of inclusion criteria. The study included three scheduled clinical visits on days 0 (screening and baseline visit), 15 (follow-up visit), and 30 (final visit). Following an assessment of baseline data, all subjects were given Roop Mantra Cucumber Ayurvedic Medicinal Face Wash for 30 days. The efficacy of Roop Mantra Cucumber Ayurvedic Medicinal Face Wash was determined by measuring changes in parameters such as skin characteristics, skin appearance, and Global Acne Assessment (GAA) score. Product safety was assessed by determining local intolerance and adverse effects of Roop Mantra Cucumber Ayurvedic Medicinal Face Wash. **Results:** The results of the study showed that applying Roop Mantra Cucumber Ayurvedic Medicinal Face Wash for 30 days significantly improved skin's characteristic and appearance. Roop Mantra Cucumber Ayurvedic Medicinal Face Wash was also found to be dermatologically well tolerated and had no negative impacts over the course of the study. **Conclusion:** The polyherbal Roop Mantra Cucumber Ayurvedic Medicinal Face Wash was found to be very safe and effective in reducing acne, pimples, blemishes, and skin dryness with improved skin texture and appearance. Roop Mantra Cucumber Ayurvedic Medicinal Face Wash is therefore a clinically feasible and safe alternative for treating the aforementioned skin conditions.

INTRODUCTION

Skin cleansers, which are widely available on the market in the form of soaps, creams, liquids, or gels play an important role in routine skin care.^[1] Skin cleansers reduce skin surface tension, making it easier to remove dirt, sebum, microorganisms, and exfoliated skin cells from the skin's surface.^[2] Furthermore, skin cleansers improve acne by removing hair follicle plugs and preventing hair follicle obstruction.^[3] More than half of women frequently use soap (ionic)-based cleansers to cleanse their faces, which can cause stratum corneum damage and extensive dryness, as

well as disruption of barrier function and changes in skin pH, lipid organization/composition, and content.^[2,4]

Sebaceous glands in the skin produce and secrete sebum, which is essential for cutaneous homeostasis by performing functions such as photoprotection, anti-inflammatory, antioxidant, antibacterial and maintaining cutaneous barrier function and hydration.^[5-7] It is excreted to the skin surface through the skin pores and the widening of these skin pores by various exogenous and endogenous factors such as gender, genetic predisposition, ageing, chronic ultraviolet light exposure, comedogenic xenobiotics, acne, and seborrhea leads to excessive sebum production and secretion.^[8] Excessive facial sebum secretion not only causes oily skin, but it also causes cutaneous problems such as skin irritation, seborrheic dermatitis, comedone formation, proliferation and cutibacterium acnes colonisation.^[9-12] The use of high-detergency skin

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cleansers is also problematic for people with little facial sebum because washing sebum well can cause skin problems such as dry xerotic skin.^[7] Many soaps and cleansers on the market are marketed as "mild," but these claims are unsubstantiated.^[13] Moisture and sebum levels are therefore an important component of a gentle skin cleanser to be used on a regular basis by people suffering from skin disorders such as oily and dry skin, acne, pimples, and so on, without compromising the skin's natural protective barrier.

The use of traditionally used medicinal plants as active ingredients in skin cleansers is gaining popularity around the world. Several medicinal plants, such as *Neem*, *Aloe vera*, *Tulsi*, *Amla*, *Manjistha*, *Eucalyptus* and others, are used in Ayurveda to treat various skin disorders due to their antioxidant, anti-inflammatory, rejuvenating, and antimicrobial properties.^[14,15] Antioxidants, anti-inflammatory, smoothing, moisturizing, and sebum secretion control are among the primary benefits of herbal skin cleansers.^[16] The Roop Mantra Cucumber Ayurvedic Medicinal Face Wash is an Ayurvedic proprietary product that contains ingredients like *Azadirachta indica* (*Neem*), *Aloe barbadensis* (*Aloe vera*), *Curcuma longa* (*Haridra*), *Rosa centifolia* (*Rose*), *Symplocos racemosa* (*Lodhra*), *Rubia cordifolia* (*Manjistha*), *Mentha piperita* (*Pudina*), and *Cucumis sativus* (*Kheera*). In India, the product is marketed for the treatment of acne, facial scars, pimples, blemishes, dull, and dry skin. The purpose of this study was to assess the safety and efficacy of Roop Mantra Cucumber Ayurvedic Medicinal Face Wash in reducing acne, facial scars, pimples, blemishes, dull and dry skin in healthy adult volunteers in order to imbibe more confidence about the promising product among consumers.

MATERIALS AND METHODS

Study Population, Screening and Enrolment

The present study involved male and female subjects who were suffering from acne, pimples, blemishes, dull and dry skin. A series of screening assessments were conducted to determine whether prospective study participants fulfilled the study's eligibility criteria. Each eligible subject was assigned a unique subject number. All study documents relating to that subject included the subject number, which was cross-referenced by the subject's initials.

Sample Size

The sample size was chosen without any statistical consideration. A convenient sample size of 120 subjects was used to assess the safety and efficacy of Roop Mantra Cucumber Ayurvedic Medicinal Face Wash.

Study Intervention

The study intervention, Roop Mantra Cucumber Ayurvedic Medicinal Face Wash (Fig 1) was manufactured and provided by Divisa Herbal Care, Chandigarh, India. Roop Mantra Cucumber Ayurvedic Medicinal Face Wash contains extracts from the following plants: *A. indica*, *A. barbadensis*, *C. longa*, *R. centifolia*, *S. racemosa*, *R. cordifolia*, *M. piperita*, and *C. sativus*. Subjects were instructed to apply a small amount of Roop Mantra Cucumber Ayurvedic Medicinal Face Wash with a small amount of water over their face and neck, massage gently in a circular motion and then rinse thoroughly with water. It was recommended that this product be used twice daily for 30 days, preferably in the morning and evening.



Fig. 1 The study product (Roop Mantra Ayurvedic Medicinal Face Wash)

Subject Selection Criteria

Inclusion Criteria

Patient inclusion criteria included healthy volunteers without serious or chronic illnesses, male or female, aged 18-45 years, who were willing to participate and voluntarily signed consent, and suffering from acne, facial scars, pimples, blemishes, dull, and dry skin.

Exclusion Criteria

Women who were pregnant or breastfeeding, as well as those who had undergone surgery or participated in another cosmetic clinical trial, were not eligible. Participants who refused to sign the informed consent form or used face bleach, facial scrub, hair removal, or any other product within two weeks of screening were excluded. Participants with a known history of psoriasis, leukoderma disorder, skin allergy, or surgery, as well as those with moles or tattoos, were excluded.

Study Design

The present study was a single-arm, single-centric, non-randomized, open-label post-marketing surveillance study. The study was conducted between November 2020 and January 2021 at the Akshatha Skin and Hair Care Centre in Bangalore, India, under strict compliance with the ICMR, ICH-GCP, and Declaration of Helsinki guidelines. The total study duration was 30 days, including three scheduled clinic visits on days 0 (screening and baseline visit), 15 (follow-up visit), and 30 (final visit). Subjects were assessed for eligibility based on inclusion and exclusion criteria after providing informed consent. The possibility of pregnancy and any allergies to internal or external factors were assessed in the eligible subjects. Physical examinations, vital signs, demographic information, and medical/surgical histories were all taken into account for each enrolled participant at the baseline visit. All participants were

instructed to record adverse events. All subjects received the study intervention for 30 days.

Primary Outcomes

Skin Characteristics

Skin characteristics were evaluated by administering self-assessment questionnaire to the participants at days 15 and 30. Participants were rating their skin characteristics as 1= dry, 2= normal, 3= combination and 4= oily skin types.

Global Acne Assessment Score

A dermatologist rated the severity of acne, pimples, and blemishes at days 15 and 30 using the Global Acne Assessment (GAA) chart. The change in mean GAA score from day 15 to day 30 was assessed. The severity of acne, pimples, and blemishes was rated on a 6-point scale (Table 1). The lower GAA score indicates the reduction in the severity of acne, blackheads, and blemishes.

Table 1: Global Acne Assessment (GAA) Grading and Scoring System

Grade	Score	Definition
Clear	0	Residual hyperpigmentation and erythema may be present
Almost clear	1	A few scattered comedones and a few (less than five) small papules
Mild	2	Easily recognizable; less than half of the face is involved. Many comedones and many papules and pustules are present
Moderate	3	More than half of the face is involved. Numerous comedones, papules, and pustules
Severe	4	The entire face is affected and covered with comedones, numerous papules and pustules, and few nodules and cysts
Very Severe	5	Highly inflammatory acne covering the face; nodules and cysts are present

Skin Appearance

Change in skin appearance from day 15 to day 30 was assessed using a self-assessment questionnaire designed according to investigator assessment parameters, including skin quality, acne and blemishes, scars, the radiance and improvement of the skin. Self-assessment questionnaire (SAQ) scores on investigator assessment parameters on a 5-point scale were used to categorize each skin parameter, where change =1, fair = 2, good = 3, very good =4, and excellent = 5. The higher SAQ score indicate the improvement of skin appearance.

Secondary Outcomes

The safety and tolerability of the study intervention were assessed at days 15 and 30 using a dermatologist's physical assessment and self-reported adverse events by participants such as erythema, dryness, oedema, urticaria, allergic reactions, and others.

Ethical Approval

This study protocol was approved by the ACE Independent Ethics Committee with Protocol No:

SBS/DIV/001/2020. The study was registered with the Clinical Trials Registry-India (CTRI Number: CTRI/2020/11/029426) on November 27, 2020.

Statistical Analysis

Demographic characteristics and results of the study were summarized with descriptive statistics including average, standard deviation (SD), frequency and percentages. Changes in the mean GAA and SAQ scores from day 15 to day 30 were assessed by paired t-test. Statistical analysis was carried out using SPSS statistical software version 23.0 (SPSS Inc., USA). The P value, 0.05, was considered statistically significant.

RESULTS

Subjects Flow and Baseline Characteristics

A total of 120 subjects were screened and enrolled for this study, with 57 (47.5%) men and 63 (52.5%) females with an average age of 28.32±8.04 years. During the study period, no participants dropped out, discontinued, or withdrew their consent. Fig 2 depicts the flow of participants.

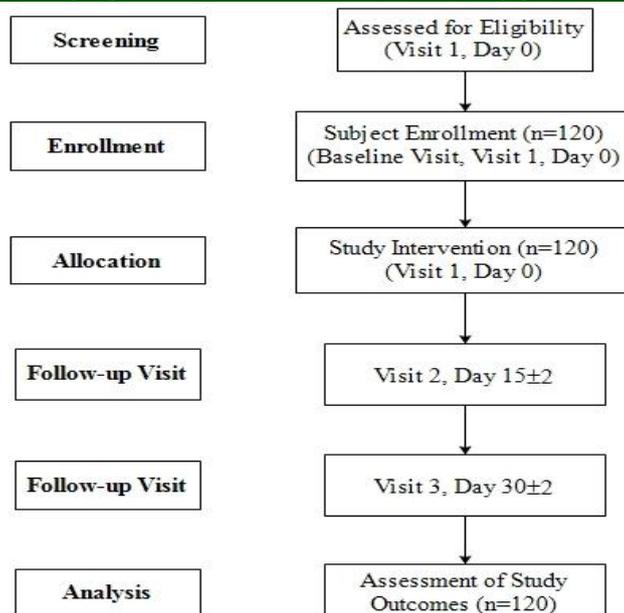


Fig. 2 Flow of Participants

Primary Outcomes

Skin Characteristics

Self-reported skin characteristics of the participants at days 15 and 30 are summarized in the Table 2. On day 15, participants' skin types were reported as oily 16.67%, combination 22.50%, dry 29.20%, and normal 31.70%. Use of Roop Mantra Cucumber Ayurvedic Medicinal Face Wash, skin characteristics changed to oily 6.67%, combination 12.50%, dry 18.32%, and normal 62.50% at day 30. A total of 75 of the 120 participants were found to have healthy, normal skin at the end of the study.

Table 2: Frequency of Skin Characteristics at days 15 and 30

Skin Characteristics	Visit 2, Day 15 (n=120)		Visit 3, Day 30 (n=120)	
	Frequency (n)	Percent (%)	Frequency (n)	Percent (%)
Oily	20	16.67	8	6.67
Combination	27	22.50	15	12.50
Dry	35	29.20	22	18.32
Normal	38	31.70	75	62.50

Global Acne Assessment (GAA)

In this study, 79 (65.83%) of the participants had acne, blemishes, or pimples. On the day 30, frequency of acne, blemishes, and pimples severity was markedly reduced compared to day 0 (Table 3). On the day 30, 16.46% of subjects had clear skin, while 41.77% had almost clear skin compared to 5.06% and 17.72 on day 0, respectively. After application of Roop Mantra Cucumber Ayurvedic Medicinal Face Wash, mean GAA score decreased significantly from 2.19 ± 0.86 (at day 0) to 1.23 ± 0.83 (at day 30). The reduction in GAA score was statistically significant [p<0.0001; mean difference, 0.962; and 95% CI, 0.83 to 1.01] (Fig 3).

Table 3: Frequency of Acne, Blemishes, and Pimples Severity at Different Visits

Symptom severity	Visit 1, Day 0 (n=79)		Visit 3, Day 30 (n=79)	
	Frequency (n)	Percent (%)	Frequency (n)	Percent (%)
Clear	4	5.06	13	16.46
Almost clear	14	17.72	33	41.77
Mild	33	41.77	21	26.58
Moderate	22	27.85	11	13.92
Severe	5	6.33	1	1.27
Very severe	0	0	0	0

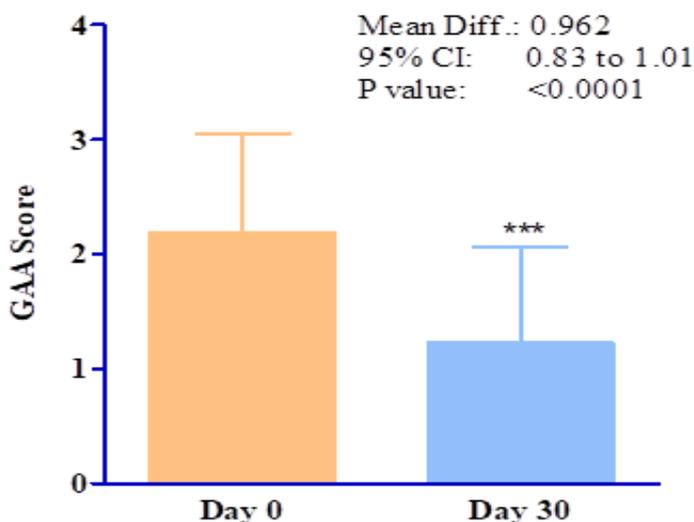


Fig. 3 Mean change in GAA score from day 0 (Visit 1) to day 30 (Visit 3)

Assessment of Skin Appearance

Results of the study showed that after application of Roop Mantra Cucumber Ayurvedic Medicinal Face Wash, around 60% of subjects reported excellent skin appearance and 14.17% reported very good skin appearance on day 30, compared to 21.67% and 12.50% on day 15, respectively (Table 4). Results of SAQ scores on skin appearance parameters including skin quality, acne and blemishes, scars, skin radiance and skin improvement are summarized in Table 5. As shown in the table 5, SAQ scores of all skin appearance parameters were significantly (< 0.0001) increased at day 30 compared to day 15.

Table 4: Frequency of Different Skin Appearances at Different Visits

Symptom severity	Day 15 (n=120)		Day 30 (n=120)	
	Frequency (n)	Percent (%)	Frequency (n)	Percent (%)
Change	19	15.83	11	9.17
Fair	20	16.67	19	15.83
Good	40	33.33	1	0.83
Very good	15	12.50	17	14.17
Excellent	26	21.67	72	60.0

Table 5: Mean change in SAQ scores from day 15 to day 30

Assessment	Day 15	Day 30	Mean diff.	95% CI	p value
	SAQ Score (Mean ± SD)	SAQ Score (Mean ± SD)			
Skin quality (n=120)	1.84±0.67	2.98±0.56	-1.14	-1.28 to -1.01	< 0.0001
Acne and blemishes (n=81)	2.17±0.70	3.19±0.74	-1.01	-1.20 to -0.83	< 0.0001
Scars (n=35)	1.97±0.57	2.77±0.55	-0.80	-1.0 to -0.60	< 0.0001
Skin radiance (n=120)	2.38±0.61	3.32±0.62	-0.94	-1.04 to -0.85	< 0.0001
Skin improvement (n=120)	2.36±0.79	3.53±0.84	-0.89	-1.03 to -0.76	< 0.0001

Secondary Outcomes

Assessment of Safety

A questionnaire was used to assess local tolerance of the study intervention on days 15 and 30 for the occurrence of erythema, dryness, oedema, urticaria, allergic responses and any other adverse effects. The subjects reported no local intolerance to the study intervention during the study period (Table 6). None of the study participants experienced any adverse reactions such as stinging, itching, or burning after using the product or at any point during the 30-day study period.

Table 6: Adverse Effects Reported to the Study Intervention

Adverse effects	Day 15 (n=120)	Day 30 (n=120)
Erythema	0/120	0/120
Dryness	0/120	0/120
Oedema	0/120	0/120
Urticaria	0/120	0/120
Allergic reactions	0/120	0/120
Any others	0/120	0/120

DISCUSSION

Herbal face wash is one of the most well-known treatments for a variety of facial skin disorders. It not only removes dirt, excess sebum, and microorganisms but also improves skin hydration and normal skin function, leading to the natural glow of the skin. In Indian traditional medicines numerous plants are used for the treatment of various skin disorders, such as *Neem*, *Aloe vera*, *turmeric*, *Manjistha*, *liquorice*, and others. These plants have been reported to provide excellent benefits for the skin.^[17] In this context, Roop Mantra Cucumber Ayurvedic Medicinal Face Wash is an Ayurvedic proprietary skincare product that contains eight medicinal plant extracts viz. *A. indica*, *A. barbadensis*, *C. longa*, *R. centifolia*, *S. racemosa*, *R. cordifolia*, *M. piperita*, and *C. sativus*. Each plant has a wide variety of therapeutic and cosmeceutical applications.

A. indica has potent antibacterial, antifungal, and anti-inflammatory properties.^[18] *A. barbadensis* promotes wound healing, skin hydration, increases skin flexibility, and decreases skin fragility.^[19,20] *C. longa* is used to treat a variety of skin conditions due to its wound healing, anti-aging, anti-inflammatory, antimicrobial, and antioxidant properties.^[21] *R. centifolia* petals are excellent for the skin because of their anti-inflammatory and antioxidant properties.^[22] *S. racemosa* is used in a number of topical herbal formulations for acne, skin disorders, and wound healing.^[23] Pharmacological studies have demonstrated the potential of *S. racemosa* as a wound healer, antibacterial, and acne treatment.^[24-26] *R. cordifolia* has important cosmeceutical applications, including the prevention of burning, itching, fungal or bacterial infection, scarring, and the promotion of skin healing through collagen formation.^[27] *R. cordifolia* extract has also been shown to have anti-acne properties.^[28,29] *M. piperita* (menthol) has antipruritic, anti-inflammatory, antibacterial, and antioxidant properties.^[30,31] *C. sativus* rejuvenates skin due to its cooling, hydrating, anti-aging, antioxidant, and anti-inflammatory properties.^[32,33]

In this study, the Roop Mantra Cucumber Ayurvedic Medicinal Face Wash was proven to be considerably effective in improving skin texture and appearance, as well as reducing acne, blemishes, and

pimples after 30 days. The effectiveness of this Ayurvedic medicinal face wash is due to the synergistic therapeutic effects of the ingredients, including anti-aging, antioxidant, anti-inflammatory, and antimicrobial properties. Furthermore, the Roop Mantra Cucumber Ayurvedic Medicinal Face Wash contains ingredients that are reported to be active against acne-causing bacteria, promote skin hydration and moisture balance, and prevent skin oiliness, redness, pigmentation, and pore clogging.

Several studies have shown that skin care or cosmetic products can have unpleasant side effects on the skin, such as allergic reactions, erythema, photoreaction, irritation, dryness and others.^[34,35] Therefore, a safety assessment of skin care products is required to determine the associated risks of the ingredients used in cosmetics. Although the adverse effects of skin care or cosmetics may differ from person to person.^[36] In this investigation, we assessed the safety of Roop Mantra Cucumber Ayurvedic Medicinal Face Wash on subjects with acne, facial scars, pimples, blemishes, dull skin and dry skin.

The results indicated that the use of Roop Mantra Cucumber Ayurvedic Medicinal Face Wash for up to 30 days had no negative effects on the skin or caused local intolerance to the study product. The main limitation of this study was its single-arm observational design without a control group. Because of this, the product's effects could not be compared to those of any other skincare product. Another drawback was the short study duration, which prevented the evaluation of long-term efficacy and safety of the product.

CONCLUSION

The results of the study revealed that the use of Roop Mantra Cucumber Ayurvedic Medicinal Face Wash on a daily basis can help to effectively reduce acne, pimples, blemishes, dullness, and dryness. Roop Mantra Cucumber Ayurvedic Medicinal Face Wash resulted in higher compliance among study subjects due to its ease of use and lack of side effects. Overall, the current study provides evidence-based results for the use of Roop Mantra Cucumber Ayurvedic Medicinal Face Wash in improving the aforementioned skin

conditions with better skin texture and appearance with no adverse effects.

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