International Journal of Research in Dermatology
Joshi R et al. Int J Res Dermatol. 2025 Jan;11(1):16-25
http://www.ijord.com

DOI: https://dx.doi.org/10.18203/issn.2455-4529.IntJResDermatol20243440

Original Research Article

A comparative evaluation of a commercially available kojic acid and arbutin-containing test product with a test regime in the treatment of hyperpigmentation

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Received: 21 October 2024
Revised: 01 November 2024
Accepted: 06 November 2024

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ABSTRACT

Background: The study compared the effectiveness of kojic acid and arbutin-containing lotion (alone) with arbutin-containing facewash and kojic acid and arbutin-containing lotion in the reduction of pigmentation.
Methods: The study compared the test product (lotion) and the test regime (lotion + facewash) over a period of 45 days. In both test groups, a thin layer of advance body lotion was applied to the face, neck, and upper trunk. In the test regime group (TRG), these areas were washed with advance facewash before the lotion was applied. Both groups used sunscreen (with a sun protection factor of 50). The primary outcomes measured were (i) skin radiance and skin pigmentation, (ii) skin gloss, and (iii) skin hydration. The secondary outcomes measured were clinical evaluation and a subjective self-assessment for tolerance and perception of the product.
Results: The study included 61 participants. The TRG showed a statistically significant increase in skin hydration (at 21 days) and skin gloss compared to the test product group (TPG) (at 21 and 45 days) ($p<0.05$). The majority of participants in both groups reported a visible reduction in pigmentation and improved facial glow and hydration as compared to baseline. No serious adverse effects were reported.
Conclusions: The use of kojic acid and arbutin-containing lotion alone and arbutin-containing facewash with the lotion led to significant improvements in skin radiance, lightening, gloss, and hydration as compared to the baseline, with the TRG showing significantly better clinical results than the TPG in terms of skin hydration and gloss.

Keywords: Arbutin, Hyperpigmentation, Kojic acid

INTRODUCTION

Treating and managing hyperpigmentation is one of the crucial goals in cosmetic formulation research. Hyperpigmentation disorders are among the most common presenting conditions in dermatology clinics.[1] Dyschromia results from alterations in various mechanisms regulating melanogenesis. Research over the years has delved into the pathophysiology of hyperpigmentation, resulting in the investigation and development of a number of agents effective in managing hyperpigmentation. Melanin, primarily responsible for hyperpigmentation, is regulated by the enzyme tyrosinase. Tyrosinase enzyme inhibitors have, therefore, become crucial components of skin-lightening agents. The first-line drugs for the management of hyperpigmentation include hydroquinone, kojic acid, and glycolic acid, followed by oral formulations. For mild cases and maintenance of remission in hyperpigmentation, skincare products containing

ingredients such as kojic acid, arbutin, and niacinamide have been found useful.[2] Hydroquinone is often considered the gold standard for the topical treatment of hyperpigmentation. However, its long-term and unsupervised use has been associated with ochronosis, among other side effects. Similarly, other conventionally used skin-lightening agents such as corticosteroids, mercury-containing compounds, glutathione, and retinoids are all associated with various deleterious side effects. Based on these data, a clear need exists for an effective, well-tolerated skin-lightening agent.[3]

Kojic acid is a skin-lightening agent discovered by Saito in 1907. It inhibits tyrosinase and hence inhibits melanin formation, and decreases hyperpigmentation. Kojic acid in topical preparations was found to be safe in chronic, reproductive, and genotoxicity aspects.[4]

Arbutin is a naturally occurring agent that effectively reduces melanin synthesis by tyrosinase inhibition. It occurs in two isoforms–α and –β with the α form being more effective in tyrosinase inhibition. Due to its molecular structure, although arbutin works in a similar manner as hydroquinone, it is not associated with exogenous ochronosis and is better tolerated.[3]

Treatment regimens for hyperpigmentation typically involve several products, including sunscreens, skin whitening agents, moisturizing products, and cosmeceuticals containing anti-inflammatory and anti-angiogenic agents. Since UV radiation is a well-known extrinsic factor in the development of hyperpigmentation, the use of broad-spectrum sunscreens is often the first choice in treating hyperpigmentation. Skin whitening agents such as niacinamide, arbutin, tranexamic acid, vitamin C, and vitamin E not only reduce melanin production but also have anti-inflammatory effects that reduce hyperpigmentation. Moisturizing products containing occlusives, humectants, emollients, and rejuvenators can help restore the skin's barrier function and reduce hyperpigmented spots or patches. Cosmeceuticals usually contain several components that often combine UV-protective, tyrosinase-suppressive, moisturizing, anti-inflammatory, and skin-repairing effects in one product.[5] In addition, liquid body washes containing mild surfactants and emollients, which help improve the skin gradually, may also be used.[6] Different topical therapies target different pathways of melanogenesis. A multimodal approach targeting other mechanisms could improve the results.[2]

However, studies comparing the efficacy of these agents in combination in a regime vs. the use of a single product alone, are few.

This study was carried out to assess the efficacy of a test regime (kojic acid and arbutin-containing lotion + arbutin-containing facewash) and a test product (kojic acid and arbutin-containing lotion) in the reduction of pigmentation. In addition, the effectiveness of each therapy was compared with the other.

METHODS

This was a trial to study the efficacy of a test regime (Biluma® advance body lotion + Biluma® advance facewash) and a test product (Biluma® advance lotion) in the reduction of pigmentation and to compare their efficacies with each other.

The lotion contains kojic acid and arbutin and the facewash contains arbutin (detailed composition is available in Appendix Table 1 and 2).

Study design

This was a monocentric, single-blinded, randomized study. The study was conducted at C.L.A.I.M.S. Pvt. Ltd. (Address: 4th floor, B wing, Modi House, C-10, Dalia industrial estate, New Link Road, Andheri (W), Mumbai-400058).

Ethical consideration

The study was approved by the institutional ethics committee. Before screening, the participants were informed about the study details, and written, informed consent was obtained.

Study population

The study involved two groups-the TPG and the TRG-and was carried out over 45 days. The details of the study population and inclusion and exclusion criteria are depicted in Figure 1.

Inclusion criteria

Patients aged 18–55 years, willing to avoid sun exposure and agreeing not to use other products with the same end benefit were included in the study.

Exclusion criteria

Patients who were on any other topical agents for the past 2 weeks, pregnant or lactating women, hypersensitive to any of the components in the products used in this study were excluded from this study. Patients on systemic therapy or taking part in any other trials that could interfere with the results of this study were excluded.

Outcome measures

The primary outcome measures of this study were: (i) measurement of skin radiance (luminosity [L*] values) and skin pigmentation (individual typology angle [ITA]) using spectrophotometer readings, (ii) measurement of skin gloss using skin glossmeter readings, and (iii) measurement of skin hydration using moisture meter score (MMSC) readings.

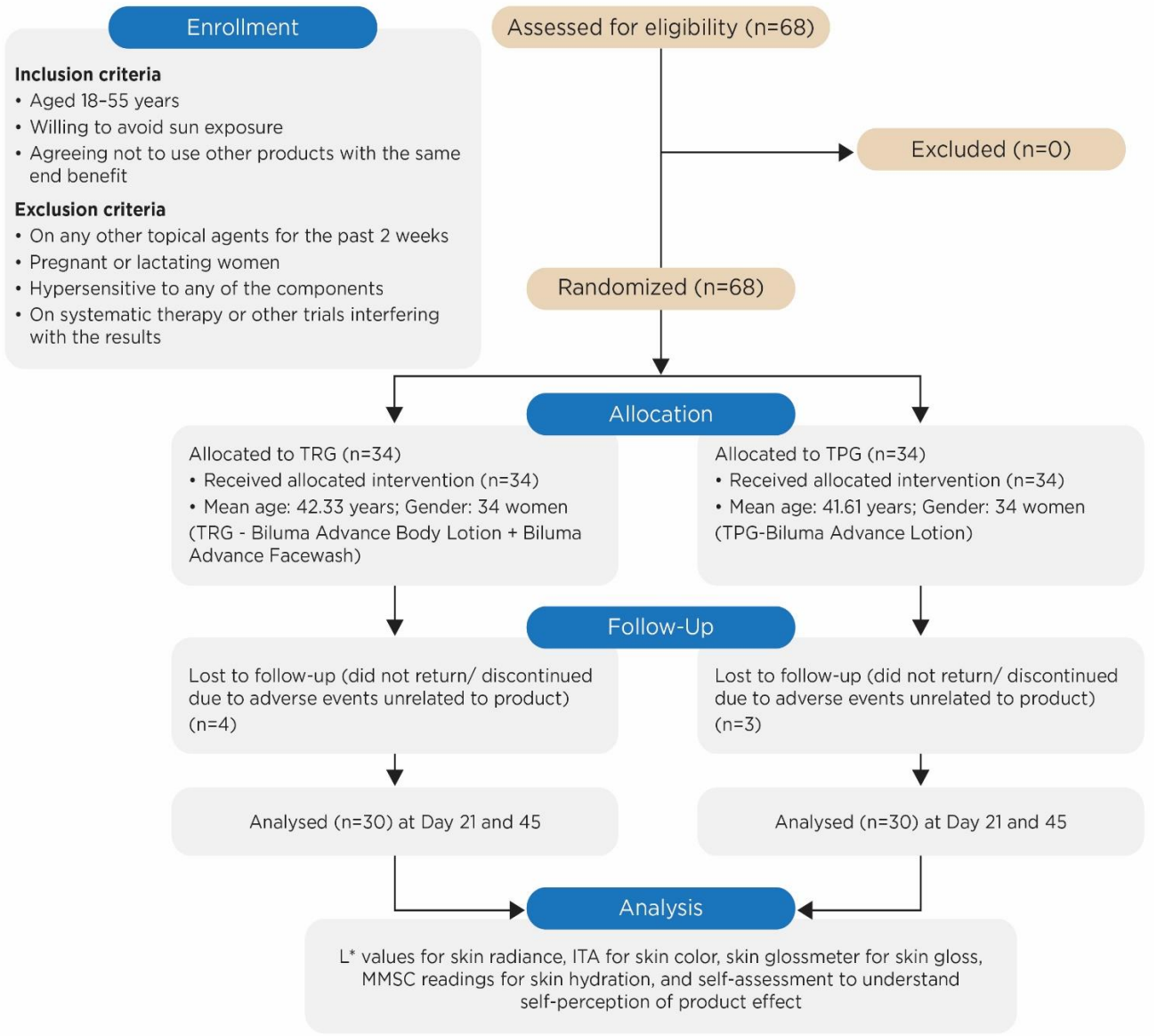

Figure 1: Consort flow diagram.

Colorimetric measurements were made using the L*a*b* colorimetric model (Commission internationale del'Eclairage). Luminescence (black to white) was represented by L*, and a and b represent two color ranges (from green to red and from blue to yellow). The L* parameter was used to assess the color brightness. The brightness varied between 100 for a white and 0 for a black surface. The ITA determined the lightness of skin color. An ITA >55° corresponded to very fair skin and an ITA<10° to very dark skin.[7] The MMSC was used to measure the hydration of the stratum corneum.[8]

A spectrophotometer (Konica Minolta) was used to measure the skin color. Light from three pulsed xenon lamps (wavelength range 360–740 nm) was diffused on the inner surface of the integrating sphere and used to illuminate the specimen uniformly. The light reflected by the specimen was received by the specimen-measuring optical system. The reflected light and the diffused light were divided into each wavelength component by the specimen-measuring optical system and illumination-monitoring optical sensor, respectively. The signal proportional to the light intensity of each component was the output to the analog processing circuit.

The SkinGlossMeter (Delfin Technologies, Kuopio, Finland) has a built-in red semiconductor diode laser (635 nm). The laser beam was directed onto the skin surface and the ratio of the intensity of the incident beam and specular reflection was used to calculate the gloss value.[9]

The Antera 3D® camera was used for image acquisition and analysis of skin features. It illuminated the surface of the skin from different angles and prepared a three-dimensional reconstruction of the skin surface. It performed the spatial and spectral analysis of the

acquired data by illuminating the skin with light emitting diodes (LEDs) of different wavelengths (455–625 nm) from different directions. The quantitative results obtained were on skin roughness, facial pore volume, and wrinkle depth and width.

Hydration was assessed using the MoistureMeter SC Instrument. MoistureMeter SC Compact (Delfin Technologies, Kuopio, Finland) measured the hydration of the skin surface (the stratum corneum). Scores for different skin types were <20 for dry skin, 20–40 for normal skin, and >40 for well-hydrated skin.

The secondary outcome measures for this study were clinical evaluation and the self-assessment questionnaire for in-use tolerance. A subjective questionnaire was used to understand the participants' perceptions of the effects of the products.

In-use tolerances for pricking, tingling, itching, and burning sensations were clinically evaluated using a scale range of 1 to 3, with 1 being slight, 2 being moderate, and 3 being severe.

Product usage

The advance body lotion was applied on the face, neck, and upper trunk (back) twice daily (morning and night before bedtime). In the case of TRG, the face, neck, and upper trunk (back) areas were washed with the Advance Facewash (approximately 5 g) and dabbed dry with a towel, before the advance body lotion was applied. In both TPG and TRG, a thin layer of the Advance Body Lotion (approximately 5 g) was applied on the face and carefully spread around the eyes, neck, and upper trunk (back) areas by gentle rubbing.

Statistical methods

Continuous variables were summarized using descriptive statistics and SPSS 10.0 was used to carry out the statistical analysis. Student's t-tests and chi-square tests were used to analyze the differences between groups, statistical tests were interpreted at a 95% confidence interval, and results with $p<0.005$ were considered statistically significant.

RESULTS

The study included 61 participants (31 women in the TPG and 30 in the TRG). The mean ages of the participants in the TPG and TRG are shown in the Table 1.

Table 1: Age distribution of participants.

Groups	N	Mean age (in years)
TPG	31	41.61
TRG	30	42.33

Mean skin radiance (L*)

After 21 and 45 days of the two treatments, mean L* values on the face, neck, and upper trunk showed a statistically significant increase in radiance values from baseline (Table 2; Figure 2A). However, between groups, there was no significant difference in L* values on the face, neck, and upper trunk.

Mean ITA values

After 21 and 45 days of the two treatments, mean ITA values on the face, neck, and upper trunk showed a statistically significant increase from baseline (Table 2; Figure 2 B). There was no significant difference in ITA values on the face and upper trunk between the groups at any time point.

Mean skin hydration

After 21 and 45 days, no significant changes in MMSC from baseline in either of the two treatments were observed at any time point in all body parts assessed. In the TPG, after 21 days of application of the body lotion, mean MMSC values on the neck and upper trunk showed no significant change from baseline. However, after 45 days, mean MMSC values on the neck and upper trunk showed a statistically significant increase of 18.6% and 17.8%, respectively, from baseline. In the TRG, after 21 and 45 days of applying the facewash and body lotion, mean MMSC values on the neck showed a statistically significant increase of 27.1% and 37.4%, respectively, from baseline. After 21 days, mean MMSC values on the upper trunk (back) showed no significant change from baseline. However, after 45 days, mean MMSC values on the upper trunk (back) showed a statistically significant increase of 24.8% from baseline (Table 2; Figure 2 C). After 21 days, the TRG showed a statistically significant improvement in skin hydration on the upper trunk compared to the TPG ($p=0.025$). In contrast, after 45 days, no significant differences in upper trunk skin hydration between the TPG and TRG were detected.

Mean skin gloss on the face

In the TPG, after 21 and 45 days of application of the body lotion, mean gloss values on the face and neck showed no significant change from baseline. However, after 45 days, mean gloss values on the upper trunk (back) showed a statistically significant increase of 5.3% from baseline. After 21 days of applying the facewash and body lotion, mean gloss values on the face, neck, and upper trunk showed a statistically significant increase of 5.2%, 5.1%, and 7.8%, respectively, from baseline. After 45 days of applying the facewash and body lotion, mean gloss values on the face, neck, and upper trunk showed a statistically significant increase of 8.9%, 7.6%, and 11.8%, respectively, from baseline (Table 2; Figure 2 D). After 21 days, there were no significant differences in

skin gloss on the face between the TPG and TRG. After 45 days, however, the TRG showed a statistically significant improvement in skin gloss on the face compared to the TPG (p=0.015). In addition, there were statistically significant improvements in the TRG compared to the TPG in skin gloss after 21 and 45 days of treatment, on the neck (p=0.012 and p=0.006, respectively) and upper trunk (p=0.003 and p=0.023, respectively).

Self-evaluation questionnaire for efficacy

Day 21-TPG: All the participants agreed that their skin felt moisturized, and 87.1% agreed that there was a visible reduction in pigmentation. About 90.3% of the participants agreed that their faces glowed.

Day 21-TRG: 86.6% of participants agreed that their skin felt moisturized, 76.6% of participants agreed that there was a visible reduction in pigmentation, and 80.0% of participants agreed that there was a glow on the face.

Day 45-TPG: 100.0% of participants agreed that their skin felt moisturized, 100.0% of participants agreed there was a visible reduction in pigmentation, and 96.8% of participants agreed that there was a glow on the face.

Day 45-TRG: 93.4% of participants agreed that their skin felt moisturized, 73.3% agreed that there was a visible reduction in pigmentation, and 90.0% of participants agreed that there was a glow on the face (Table 3).

Clinical evaluation for tolerance

Based on the evaluation questionnaire for in-use skin tolerance, one participant from the TRG reported slight itching on days 21 and 45, and one reported a slight burning sensation on day 21. There were three adverse events during the study period. One participant from the TPG developed pityriasis rosea and two participants from the TRG developed mild acneiform eruptions. All adverse events were resolved after discontinuing the treatments. No severe adverse events were reported throughout the study.

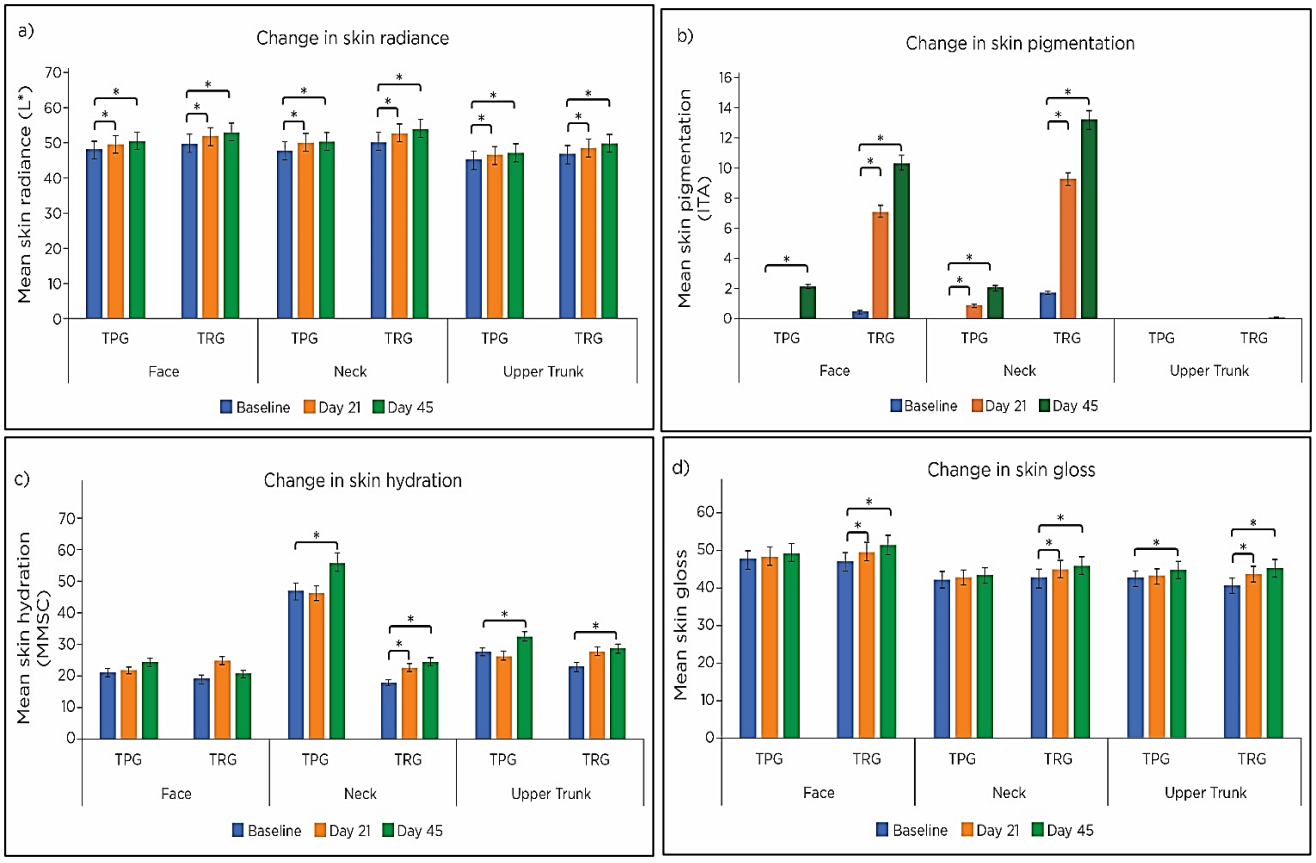

Figure 2 (a-d): Changes in mean skin radiance at 21 and 45 days as compared to the baseline. Changes in mean skin pigmentation at 21 and 45 days as compared to the baseline. Changes in mean skin hydration and gloss at 21 and 45 days compared to the baseline. Changes in mean skin gloss at 21 and 45 days compared to the baseline.

Table 2: Changes in mean L*, mean ITA, mean MMSC, and mean skin gloss on the face, neck, and upper trunk (back).

Variables	Duration (days)		Baseline	Day 21	Day 45	Mean diff. (baseline-day 21)	P value	Mean diff. (baseline-day 45)	P value
Mean skin radiance (L*) (X̄±SD)	Face	TPG (n=31)	48.58±4.18	49.96±3.94	50.86±4.04	*1.38±3.25	0.024	*2.28±3.31	0.001
		TRG (n=30)	50.24±3.75	52.29±3.30	53.54±3.37	*2.06±2.55	0.001	*3.31±2.34	0.001
	P value		0.107 (NS)			0.366 (NS)		0.164 (NS)	
	Neck	TPG (n=31)	48.31±5.23	50.45±4.14	50.97±3.99	*2.14±3.22	0.001	*2.67±3.60	0.001
		TRG (n=30)	50.62±3.84	53.16±3.48	54.48±3.17	*2.54±2.79	0.001	*3.85±3.11	0.001
	P value		0.053 (NS)			0.605 (NS)		0.175 (NS)	
	Upper trunk	TPG (n=31)	45.66±3.88	46.85±3.77	47.76±3.90	*1.19±2.24	0.005	*2.10±2.81	0.001
		TRG (n=30)	47.37±4.08	49.06±4.25	50.15±4.00	*1.69±1.57	0.001	*2.78±1.63	0.001
	P value		0.099 (NS)			0.315 (NS)		0.250 (NS)	
Mean skin pigmentation (ITA) (X̄±SD)	Face	TPG (n=31)	-04.58±13.02	-00.50±12.68	02.22±12.63	*04.08±10.15	0.032	*06.80±10.48	0.001
		TRG (n=30)	00.55±11.80	07.18±10.49	10.37±10.21	*06.63±08.12	0.001	*09.82±07.41	0.001
	P value		0.112 (NS)			0.282 (NS)		0.197 (NS)	
	Neck	TPG (n=31)	-05.67±16.30	00.97±11.69	02.17±11.59	*06.64±10.49	0.001	*07.84±11.84	0.001
		TRG (n=30)	01.78±11.74	09.30±10.35	13.23±09.56	*07.52±08.64	0.001	*11.45±09.34	0.001
	P value		*0.044						
	Upper trunk	TPG (n=31)	-3.48±12.30	-09.70±11.91	-07.15±12.21	*03.78±07.36	0.007	*06.33±08.93	0.001
		TRG (n=30)	-08.14±12.48	-02.96±12.78	00.12±11.94	*05.18±04.89	0.001	*08.27±05.09	0.001
	P value		0.097 (NS)			0.384 (NS)		0.299 (NS)	
Mean skin hydration (MMSC) (X̄±SD)	Face	TPG (n=31)	21.48±11.10	21.97±11.25	24.75±13.41	00.49±10.22	(0.791) NS	03.27±11.79	(0.133) NS
		TRG (n=30)	19.65±13.30	25.10±18.73	20.92±13.18	05.46±16.09	(0.073) NS	01.28±14.82	(0.639) NS
	P value		0.562 (NS)			0.156 (NS)		0.564 (NS)	
	Neck	TPG (n=31)	47.57±18.70	46.60±15.04	56.42±17.71	-00.98±14.75	(0.713) NS	*08.85±14.22	-0.001
		TRG (n=30)	17.99±10.17	22.87±10.30	24.70±13.01	*04.88±08.24	-0.002	*06.72±11.85	-0.004
	P value		*0.001						
	Upper trunk	TPG (n=31)	27.93±10.38	26.67±09.52	32.91±12.44	-01.26±06.69	(0.302) NS	*04.98±08.58	-0.002
		TRG (n=30)	23.25±12.93	28.16±12.44	29.01±11.64	04.91±13.23	(0.051) NS	*05.76±13.02	-0.021
	P value		0.125 (NS)			*0.025		0.784 (NS)	
Mean skin gloss (X̄±SD)	Face	TPG (n=31)	48.35±06.35	49.22±06.31	49.95±05.50	00.86±04.43	(0.288) NS	01.59±04.91	(0.081) NS
		TRG (n=30)	47.93±05.81	50.41±06.29	52.19±05.92	*02.48±02.27	-0.001	*04.26±03.37	-0.001
	P value		0.788 (NS)			0.076 (NS)		*0.015	
	Neck	TPG (n=31)	42.89±04.36	43.46±04.25	43.98±04.66	00.57±03.14	(0.320) NS	01.09±03.89	(0.129) NS
		TRG (n=30)	43.42±03.44	45.66±03.76	46.71±03.33	*2.23±01.68	-0.001	*3.29±01.87	-0.001
	P value		0.600 (NS)			*0.012		*0.006	
	Upper trunk	TPG (n=31)	43.01±04.06	43.72±03.96	45.31±04.62	00.71±03.72	(0.296) NS	*02.30±04.87	-0.013
		TRG (n=30)	41.14±04.99	44.34±04.46	46.00±04.92	*03.20±02.62	−0.001	*04.86±03.64	-0.001
	P value		0.114 (NS)			*0.003		*0.023	

By student t-test, *Significant, NS=Not significant. ITA: Individual typological angle; L: Luminescence/radiance scale; MMSC: Moisture meter score; SD: standard deviation; TPG: Test product group; TRG: Test regime group.

Table 3: Results of the self-evaluation questionnaire for efficacy after 21 and 45 days.

Assessments				Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Top 2 boxes (agree + strongly agree)
Skin feels moisturized	TPG, (n=31)	Day 21	N	-	-	-	*25	*06	31
			(%)	-	-	-	80.6	19.4	100
		Day 45	N	-	-	-	20	11	31
			(%)	-	-	-	64.5	35.5	100
	TRG, (n=30)	Day 21	N	-	-	4	13	13	26
			(%)	-	-	13.4	43.3	43.3	86.6
		Day 45	N	-	-	2	14	14	28
			(%)	-	-	6.6	46.7	46.7	93.4
Visible reduction in pigmentation in the face	TPG, (n=31)	Day 21	N	-	-	4	20	7	27
			(%)			12.9	64.5	22.6	87.1
		Day 45	N	-	-	-	*17	*14	31
			(%)	-	-	-	54.8	45.2	100
	TRG, (n=30)	Day 21	N	-	2	5	13	10	23
			(%)	-	6.7	16.7	43.3	33.3	76.6
		Day 45	N	-	-	5	13	12	25
			(%)	-	-	16.7	43.3	40	83.3
Glow on the face	TPG, (n=31)	Day 21	N	-	2	1	27	1	28
			(%)	-	6.5	3.2	87.1	3.2	90.3
		Day 45	N	-	1	1	*22	*07	29
			(%)	-	3.2	3.2	71	22.6	93.6
	TRG, (n=30)	Day 21	N	-	2	4	9	15	24
			(%)	-	6.7	13.3	30	50	80
		Day 45	N	-	-	8	10	12	22
			(%)	-	-	26.7	33.3	40	73.3
Skin appears better than before	TPG, (n=31)	Day 21	N	-	-	1	26	4	30
			(%)			3.2	83.9	12.9	96.8
		Day 45	N	-	-	1	22	8	30
			(%)	-	-	3.2	71	25.8	96.8
	TRG, (n=30)	Day 21	N	-	1	2	16	11	27
			(%)	-	3.3	6.7	53.3	36.7	90
		Day 45	N	-	-	3	14	13	27
			(%)	-	-	10	46.7	43.3	90

*TPG: Test product group; TRG: Test regime group. Different parameters of evaluation questionnaires were analyzed using a scoring scale of 1 to 5, where 1=strongly disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, and 5= strongly agree.

DISCUSSION

Kojic acid (5-hydroxy-2 hydroxymethyl-4-pyrone) has been used in skin-lightening products in Japan since 1988.[2] It is derived from fungi such as *Acetobacter, Aspergillus*, and *Penicillium*. Due to its extensive use in foods (bean paste, soy, and sake) and cosmetic products, kojic acid is considered a safe additive in creams, lotions, serums, and soaps that can be routinely used on the face and hands.[2]

Arbutin, the β-D-glucopyranoside derivative of hydroquinone, is derived from plants such as bearberry (*Arctostaphylos uva-ursi*), blueberry, cranberry, and pear trees. Arbutin is used to treat cutaneous hyperpigmentation conditions such as melasma and UV-induced ephelides.[2] The scientific committee on consumer safety has deemed α-arbutin safe for cosmetic products.[10]

Kojic acid and arbutin inhibit tyrosinase (essential for melanin synthesis) by chelating copper.[11] This study compared the efficacy of an advance body lotion (containing kojic acid and arbutin) alone and advance body lotion (used by the TPG) with a combination of the same lotion and an arbutin-containing facewash (used by the TRG) in improving various skin parameters to test the effectiveness of the two treatments in treating skin hyperpigmentation.

The results of this study show that an advance body lotion alone (used by the TPG) and advance body lotion + advance facewash (used by the TRG) can significantly improve skin radiance, color, moisturization, and glow at the end of 45 days as compared to the baseline. However, the improvement in skin hydration and gloss was higher in people who used the advance body lotion + facewash than when the advance body lotion was used alone.

The TPG showed an increase of 2.8% and 4.7% in skin lightening (mean L* values) after 21 and 45 days, respectively. This increase was statistically significant ($p=0.001$ for both 21 and 45 days compared to baseline). The TRG also showed a statistically significant increase ($p=0.001$) from baseline to 21 and 45 days, with mean L* values showing an increase of 4.1% and 6.6% from baseline, respectively.

The results of this study match those of another study where azelaic acid and kojic acid showed significant skin lightening in comparison to untreated controls.[12]

Although an intergroup comparison showed no statistically significant results ($p=0.605$ for 21 days and $p=0.175$ for 45 days), the TRG showed clinically increased luminosity. This result may be due to the use of facewash in the TRG, which removed dirt, sebum, microorganisms, and exfoliated cells.

The mean ITA (skin lightening) difference from baseline for the TPG and TRG after 21 and 45 days was statistically significant. However, compared against each other, there was no significant difference between the groups at either time point. These results are in line with those of a 12-week, paired, double-blind study on 80 people with dyschromia, which showed that a preparation containing kojic acid, *Phyllanthus emblica* extract, and glycolic acid with 4% hydroquinone was effective in lightening hyperpigmented skin.[1]

The statistically significant increase in moisturization at day 45 in the TPG and TRG is due to the moisturizing ingredients like glycerin, butylene alcohol, and *Morus alba* leaf extract in the body lotion and the additional effect of panthenol in the facewash. This is supported by an open-labeled, randomized intraindividual trial that had shown that the reduction in trans epidermal water loss was higher in skin treated with panthenol-based skin emollients.[13] In addition, skin hydration was found to increase with the long-term use (6 weeks) of glycerol-based cream, and the hydration effect continued to persist even in the washout period.[14] Thus, the moisturizing effect of the two treatments in this study was likely due to the presence of glycerin and panthenol in the lotion.

In this study, the MMSC results on differences in skin hydration between the TPG and TRG were not statistically significant, except in the upper back area at 21 days ($p=0.025$), where the TRG showed better hydration than the TPG.

The mean gloss values on the spectrophotometer for TPG showed no significant change from baseline after both days 21 ($p=0.288$) and 45 ($p=0.081$). In the TRG, there was a statistically significant increase of 5.2% (at 21 days) and 8.9% (at 45 days). Intergroup analysis showed a statistically significant increase in gloss in the TRG group on the neck ($p=0.012$) and upper back ($p=0.003$) at 21 days, on the neck ($p=0.006$) and back ($p=0.023$) at 45 days, and on the face ($p=0.015$) at day 45. A systematic review reported similar results to those of this study on the effects of natural ingredients (specifically arbutin and kojic acid) on hyperpigmentation by increasing skin penetration and improving skin lightening.[1]

Self-assessments showed that in both groups, the majority of the participants felt that there was a visible reduction in pigmentation and improved facial glow and hydration on days 21 and 45 as compared to the baseline. Our results are similar to those of a randomized, placebo-controlled, double-blind trial that reported arbutin as showing a statistically significant clinical effect in brightening and evening skin tone in women with melasma and lentigo solaris.[15]

The efficacy of skincare products and procedures may be assessed by *in vitro* studies, self-assessment, expert evaluation, and objective instrumental measurements. The sensitivity and objectivity of instrumental measurements are high. However, non-instrumental expert evaluation is equally important. Instrumental methods to gain data add quantification to the subjective

assessment by the consumers and expert evaluators. A visual or tactile examination may not be sufficient in revealing changes in the skin's functional properties obtained by self-assessment. Consistency in results by multiple approaches, such as using instruments, self-assessments, and expert evaluators, increases the confidence on the observations.[16]

This study concludes that the TRG appears to have a better outcome on the overall complexion than TPG as per instrumental measurements.

The reported adverse reactions-pityriasis rosea and acneiform eruptions-resolved after discontinuing the products. There was no severe adverse reaction reported throughout the study.

Limitations

The small sample size and short follow-up time in this study limits the generalizability of the results obtained. Studies with larger sample sizes and of longer duration are needed to confirm the results obtained here.

CONCLUSION

The test product (body lotion alone) and test regime (body lotion and facewash) demonstrated a statistically significant improvement in skin radiance, color, moisturization, and glow at the end of the study as compared to the baseline. Regarding skin hydration and gloss, the regime showed better results clinically and statistically as compared to body lotion alone. When self-assessed by participants, no intergroup difference was found in MMSC. This study is one of the few evaluating the beneficial effects of kojic acid and arbutin independently and in combination and fills an important void in research on these agents. Longitudinal studies could further ascertain the long-term effects of kojic acid, arbutin lotion, and arbutin facewash on skin parameters.

ACKNOWLEDGMENTS

The authors would like to thank to BioQuest Solutions for editorial assistance.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Joshi R, Sen D, Choudhary S. A comparative evaluation of a commercially available kojic acid and arbutin-containing test product with a test regime in the treatment of hyperpigmentation. Int J Res Dermatol 2025;11:16-25.

APPENDIX

Table 1: Composition of advance body lotion.

INCI name	Ingredient	Function
Kojic acid	Kojic acid dipalmitate	Skin lightening
Arbutin	Arbutin	Skin lightening
Ethylhexyl methoxycinnamate	Escalol 557	UV filter
Glycerin	Phytexcell mulberry	Skin lightening moisturizing
Butylene glycol		
Water		
***Morus alba* leaf extract**		
Tocopheryl acetate	Vitamin E acetate	Antioxidant
Tetrahydrocurcumin	Sabiwhite (tetrahydrocurcumin)	Skin lightening and antioxidant
***Artocarpus lakoocha* wood extract**	*Artocarpus* extract (oxyresveratrol 95%)	Skin lightening and antioxidant
***Glycyrrhiza glabra* (licorice) root extract**	Licorice extracts 40%	Skin whitening and anti-inflammatory

Table 2: Composition of advance face wash.

INCI name	Ingredient	Function
Carbomer	Carbopol 980	Gelling agent (thickener)
Sodium hydroxide	NaOH 10% aq. Sol.	pH adjuster
Panthenol	D-Panthenol	Moisturizer
Sodium laureth sulfate	SLES (26%)	Surfactant
Decyl glucoside	Plantacare 2000 UP	Surfactant
Phenoxyethanol	Phenoxyethanol	Preservative
Methyl paraben	Methyl paraben	Preservative
Propyl paraben	Propyl paraben	Preservative
Perfume	Fragrance olive bouquet	Fragrance
Polysorbate 80	Polysorbate 80	Surfactant
Propylene glycol	Propylene glycol	Cosolvent
Microcrystalline cellulose	Golden beads	Exfoliants
Mannitol		
Hydroxypropyl methylcellulose		
Tocopheryl acetate		
Cl 77489		
Cl 77019		
Titanium dioxide		
Tin oxide		
***Aloe barbadensis* leaf juice**	Aloe vera gel	Antibacterial and soothing effect
Arbutin	Arbutin	Skin lightening
Tetrahydrodiferuloylmethane	SabiWhite (tertahydrocurcumin)	Skin lightening and antioxidant
Glycyrrhiza glabra	Licorice extract 40%	Skin whitening and anti-inflammatory
Aqua	Purified water	Solvent