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Clinical evaluation of the safety and therapeutic potential of an Ayurvedic lotion, Ayush AGT, in mild to moderate dandruff -an open-label prospective single-arm multicenter exploratory study

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Dandruff is a common skin condition that can significantly impact quality of life. An ideal anti-dandruff treatment should effectively relieve symptoms such as flaking, itching, dryness, and excessive oiliness, while promoting a healthy scalp and encouraging consistent use. This study aimed to clinically evaluate the therapeutic effect and safety of the Ayurvedic lotion Ayush AGT in managing dandruff. The study was conducted at three CCRAS institutes, (RARI Ahmedabad, RARI Vijayawada and CARI Bengaluru) with sample size 150 (50%). Participants with mild to moderate dandruff assessed by mean ASFS across 8 scalp zones with dandruff restricted to scalp were enrolled. Participants were dispensed AYUSH-AGT lotion, and instructed to use lotion every alternate day for 30 days. Outcomes were assessed using ASFS, Quadrant Area Severity Scale and DLQI every 15 days upto 45 days. Pre-post differences were assessed using paired t-test for normally distributed data and Wilcoxon signed-rank test for non-normally distributed data. Data of 143 participants were analyzed and the mean age was 29.29±8.545, with predominantly female distribution. The mean ASFS score significantly decreased from 15.70±4.380 at baseline to 5.41±3.979 at day 30 ($p<0.001$) and 4.80±4.103 at day 45 ($p<0.001$), indicating potential clinical effect of Ayush AGT on dandruff severity. QASS scores significantly decreased from 12.78 at baseline to 7.82 (day 15), 4.11 (day 30), and 3.33 (day 45) ($p< 0.001$). The DLQI score significantly decreased from 7.06±3.923 at baseline to 2.18±2.013 at day 30 ($p<0.001$), further reducing to 1.85±1.879 at day 45 ($p<0.001$), indicating reduced impact on daily activities. The study demonstrates that Ayush-AGT is an effective, easy and safe for mild to moderate dandruff.

Keywords: *Ayurveda*, Ayush AGT, Dandruff, *Darunaka*, Herbal lotion

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Dandruff is one of the most common chronic scalp condition in adults. It is estimated to affect more than half of the world's population and cause significant psychological and social distress[1]. Dandruff is limited to the scalp, and the main signs and symptoms include skin flaking, which appears as loose, or adherent small white or grey flakes, pruritis, and mild inflammation[2]. The etiopathogenesis of dandruff is believed to be multifactorial, with various theories suggesting an overlap of etiologies like colonization by Malasezzia or other yeast species, imbalance of bacterial species, disrupted epidermal barrier function, increased sebum-derived fatty acid metabolites, and peroxidation of sebum component (squalene), perivascular leukocyte infiltration which may result in mild scalp inflammation[3-5]. Various studies suggest that the immune response mounted by the host to different etiologies, psychological state, neurogenic, and nutritional factors play a significant role in individual

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susceptibility[2]. Although the precise sequence of pathogenic events in dandruff is unclear, it is evident that the scalp's immune-inhibitory environment becomes disrupted early in the disease process, leading to an intensified inflammatory response. Maintenance of scalp homeostasis, restoration of normobiosis, and resolution of scalp symptoms are very significant in the management of dandruff to prevent recurrence. Treatments to control dandruff mainly include keratolytic, antimicrobial, and anti-proliferative agents[6]. A vast majority of shampoos and other cosmeceuticals contains antifungal agents which regulate the scalp microcosm. A wide variety of scalp care products, including shampoos, creams, and lotions, are marketed and sold globally. Due to the specific nature of dandruff and the delicate balance of the scalp environment, long-term treatment and care are often required to manage the condition effectively. Skin irritation, dry skin, oily or dry hair/scalp, or hair fall are infrequently reported with the use of anti-dandruff agents.

Common dermatological disorders are usually well manageable with Ayurveda treatment, especially dandruff. Herbal cosmeceuticals have established a significant presence in the global market for common skin conditions such as acne and dandruff. Traditional use of home remedies and herbal preparations containing ingredients like neem, turmeric, and aloe has long been practiced, often without notable adverse effects and with the potential to help regulate the scalp's microenvironment. The search for herbal products that can effectively treat dandruff without side effects remains an active area of research. Ayurveda has attributed the etiopathogenesis of dandruff to the imbalance between *Vata Dosha* and *Kapha Dosha*, and the inflammatory process is the distinctive feature of *Pitta Dosha* involvement. Local and systemic treatment modalities are delineated for managing dandruff in Ayurveda classics. But herbal products like shampoo and lotions that diverge from the classical formulations are much preferred in the present scenario due to various advantages like ease of application and rinsing, better stability and shelf life, less noticeable smell, and consumer preference.

Ayush AGT is a herbal lotion developed by CCRAS for dermatological disorders. Ayush AGT underwent preclinical safety and efficacy studies before its potential for treating dandruff was explored in this proof-of-concept study.

Objectives

Primary objective

The primary objective was to assess the therapeutic effect of an herbal lotion, Ayush AGT, in the management of dandruff.

Secondary objective

The secondary objective was to demonstrate the safety of the herbal lotion, Ayush AGT, in dandruff.

Materials and Methods

Study design

The study design is a prospective, multicentre, open-label single-arm exploratory study.

Study setting

The study was conducted at three institutes of the Central Council for Research in Ayurvedic Sciences (CCRAS), *viz*., Regional Ayurveda Research Centres at Ahmedabad, and Vijayawada and the Central Ayurveda Research Institute at Bengaluru. Participants attending the OPD facilities of study sites and fulfilling the selection criteria were recruited for participation in the study. Potential participants were provided with sufficient information about the study, and only those who agreed to participate in the study and sign the informed consent form were enrolled. The study was done in accordance with the Good Clinical Practice (GCP) terms and the Ethical Guidelines for Biomedical Research on Human Participants-ICMR (2017).

Eligibility criteria

Inclusion criteria

Individuals aged 20-50 years of either gender, with mild to moderate dandruff based on the mean total Adherent Scalp Flaking Score (ASFS) of 8 zones on the scalp, and exhibiting symptoms of itchy, flaking skin confined to the scalp without visible inflammation, and willing to participate in the study for six weeks were enrolled in the study.

Exclusion criteria

Individuals with severe dandruff; individuals exhibiting itching, flaking, pruritis, or visible inflammation over the face, retro-auricular area, and upper chest; and those with a known history of psoriasis or presenting with inflammatory or infective scalp conditions were excluded from the study. Individuals with endocrine-related diseases such as thyroid disorders which may contribute to hair loss

or those with uncontrolled Diabetes Mellitus characterized by HbA1C levels exceeding 8% and a documented history of hypersensitivity to hair products; and any other medical condition deemed by the Principal Investigator to potentially jeopardize the study were also considered as grounds for exclusion.

Intervention

The Ayush-AGT lotion, was developed by the CCRAS, with turmeric (*Curcuma longa* L.) and aloe vera (*Aloe barbadensis* Miller) as active ingredients in an aqueous base. The study intervention had demonstrated anti-inflammatory activity and mild wound healing activity in pre-clinical studies and it was found to be safe in acute and sub acute dermal toxicity studies. Participants were instructed to apply the lotion to their scalp every other day, leaving it on for one hour before rinsing, adhering to this routine for a duration of one month. Throughout the trial, participants were explicitly prohibited from using any other lotions or shampoos. They were required to solely rely on the investigational product, Ayush AGT, for the intervention period. Moreover, participants were instructed to promptly report any adverse events experienced during the study period, such as itching, inflammation, or hair fall. In the event of symptom aggravation necessitating rescue medication, participants were advised to contact the investigator for further guidance and assistance. Though the lotion was directed for use for 30 days, the participants were instructed to attend a follow up at Day 45 to assess the sustained remissive effect of the intervention. Each participant received a compliance form to self-report their utilization of Ayush-AGT. To continue participation in the study, a compliance rate exceeding 80% was mandated.

Outcomes

Primary outcomes

The primary outcome of the study was to assess the therapeutic effect of Ayush AGT Lotion in dandruff by means of Adherent Scalp Flaking Score (ASFS)[7] assessed at every 15th day follow-up from baseline to day 45.

Secondary outcomes

Symptomatic improvement in Ayurvedic symptoms of *Darunaka* (dandruff) such as *Kesabhumi Prapatana* (flaking of scalp), *Kandu* (itching in scalp) and *Rukshata* (dryness of scalp) by using Visual Analogue Scale (VAS), improvement in Quadrant Area Severity Scale and improvement in Dermatology Life Quality Index (DLQI) at every 15 days from baseline till 45 days were included as secondary outcomes[8,9]. Any adverse effects such as skin irritation or complaints related to the use of the trial intervention were also to be evaluated at every fortnightly follow-up.

Safety assessment

Any adverse events reported by the participants were to be duly recorded in the adverse event reporting format, with details including name of the participant, the adverse event, the date of onset, severity, relatedness, severity, and treatment done.

Participant timeline

After the initial screening as per the selection criteria, the participants were enrolled in the study (day 1), and the data pertaining to participant demographics, clinical examination, and disease specific assessment were assessed and recorded in structured case record forms. Disease severity was assessed using ASFS, Quadrant Area Severity Scale and Quality of life assessment through DLQI at the baseline along with VAS rating for Ayurveda symptom assessment. The participants were followed-up at day 15 and day 30. After stopping of Ayush-AGT, the participants were directed to attend a follow-up on day 45. The disease specific outcome assessment such as ASFS, and DLQI were assessed at every follow-up.

Sample size

On the basis of assumption that a relevant change of 15 points would be detected in the primary outcome measure, ASFS score, at the end of the study compared with the baseline and considering a standard deviation of 35 points with 95% confidence level (α=0.05) and 80% power, the sample size was calculated as 42.73. Assuming a dropout rate of 20% (8.54), the total sample size was calculated as 51, rounded off to 50. So, 50 participants were intended to be enrolled from each of the study sites with a total target sample size of 150 from 3 study sites.

Data collection methods

Data for this study was meticulously documented using both specifically designed Case Report Forms (CRFs) and electronic CRFs (e-CRFs), ensuring adherence to the stringent standards outlined by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and GCP guidelines.

Data management

Data management procedures involved completion of source documents upon collection of case data, which were subsequently transcribed into the CRF and electronic case record form. All source documents were stored securely at the study sites for review by monitoring or auditing teams and ethical committees, as necessitated by regulatory guidelines. Access to the data was granted to research personnel according to tasks delegated by the Principal Investigator and to the statistician for data analysis.

Data monitoring

The monitoring team from CCRAS conducted monitoring to ensure the quality and scientific integrity of the clinical study. During the monitoring, conduct of the study, adherence to clinical study protocol, CRF's, informed consent forms, compliance forms, and adverse event were thoroughly reviewed.

Statistical methods

Demographic characteristics and study results were summarized using mean±standard deviation (SD) for continuous variables and frequency with percentages for categorical variables. Significance was evaluated at a 5% level ($p \leq 0.05$) with a corresponding 95% confidence interval (CI). Pre-post differences were assessed employing paired t-test for normally distributed data and Wilcoxon signed-rank test for non-normally distributed data. changes in key outcome measures, such as the Adherent Scalp Flaking Score (ASFS), Quality of Adherent Scalp Scale (QASS), and Dermatology Life Quality Index (DLQI), throughout the study duration up to day 45, were analyzed using analysis of variance (ANOVA) test.

Ethics

Approval of the Institutional ethics committee of each of the three study sites was obtained. The study protocol was registered with CTRI with registration number CTRI/2020/03/024092. The study outcomes will be disseminated through peer-reviewed journals.

Post-trial care

Subsequent management of the trial participants who completed trial participation and requiring further care was done according to the participant's symptoms, if any, and customized as per Ayurveda treatment principles for the disease.

Results

During the enrollment phase spanning from April 2021 to September 2022, a total of 170 participants underwent screening for eligibility. Of these, 150 individuals met the predefined selection criteria and were then enrolled in the study. Over the course of the study period, which concluded in September 2022, 143 participants successfully completed all study procedures. However, 7 participants dropped out from the study, among which 04 cited the COVID-19 pandemic as the reason for discontinuation, while 3 participants were lost to follow-up (Fig. 1).

The study population consisted of individuals with mild to moderate dandruff, with a mean age of 29.29 (±8.545) years, indicating a relatively young demographic. Gender distribution revealed a predominance of female participants, constituting 62.2% of the cohort. Educational attainment among participants was notably high, with 54.5% having completed undergraduate degrees and 25.9% holding postgraduate qualifications, reflecting a well-educated sample. Socioeconomic status analysis demonstrated that the vast majority of participants (89.5%) were situated above the poverty line and the majority of participants resided in urban areas (88.1%), indicating a predominantly urban-dwelling cohort. A significant proportion of participants identified as Hindu (97.9%). Majority of the participants were *Dwandaja Dosha Parkriti*, *viz.*, *Vata-Kaphaja* (30.8%), *Pitta-Kaphaja* (28.7%), or *Vata-Pittaja* (22.4%).

The condition's onset was reported to be either acute (49.3%) or chronic (50.3%), with both categories evenly represented within the study population. 91.6% of the population reported as having no addictions. Majority of participants opted

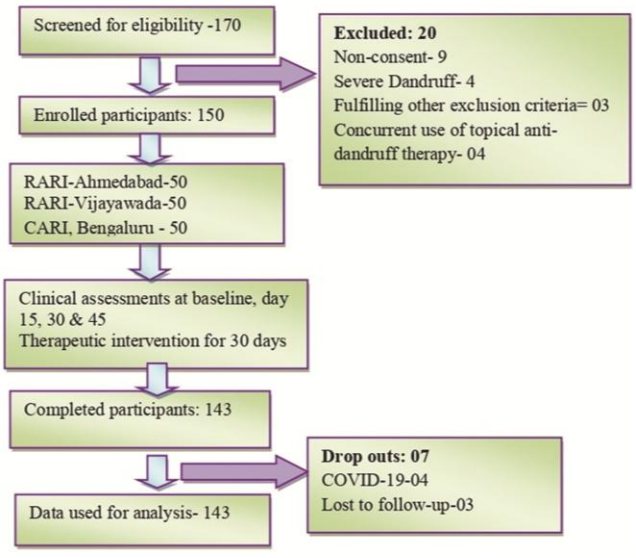

Fig. 1 — Participant outflow on the study

for head baths at a frequency of either 3-4 times per week (49%) or once per week (30.8%). Similarly, application of hair oil was reported at a frequency of either 3-4 times per week (38.5%) or once per week (39.8%) and it was interesting to note that 6.3% of the population does not apply oil at all. Coconut oil was the most commonly used hair oil (65%), followed by market brought oils (22.4%) and traditionally prepared herbal oils (9.1%). 95.8% of the participants reported using shampoos for washing hair. Only 11.9% of the participants reported to have been using hair serum or gels in hair. Table 1 presents the baseline characteristics of the study participants.

At baseline, participants exhibited a mean ASFS score of 15.70±4.380, which notably reduced to 9.27±4.486 by day 15 and further decreased to 5.41±3.979 by day 30 of the intervention. This statistically and clinically significant decline suggests a consistent improvement in dandruff severity with the application of Ayush-AGT lotion. The follow-up assessment at day 45, 15 days after cessation of lotion usage, revealed a sustained remissive effect, with the ASFS score dropping to 4.80±4.103, with a statistically highly significant reduction ($p<0.001$). At baseline, participants exhibited a mean QASS of 12.78±6.084 which then decreased significantly to 7.82±4.816 on day 15, reflecting a marked improvement in dandruff severity following the initiation of treatment with Ayush-AGT lotion. This trend continued on day 30, with the mean QASS further declining to 4.11±3.315, demonstrating sustained therapeutic effect over the intervention period. At the 45th day follow-up, the mean QASS remained low at 3.33±3.224, highlighting a sustained therapeutic effect even after the cessation of treatment. At baseline, the mean DLQI value was 7.06±3.923, indicating a mild impact of dandruff on participants' quality of life. By day 15, the mean DLQI value decreased significantly to 4.27±3.074, reflecting an early improvement in quality of life following the initiation of treatment. This improvement continued over the intervention period, with the mean DLQI value further decreasing to 2.18±2.013 by day 30 and 1.85±1.879 by day 45, both statistically significant with $p<0.001$. The impact of Ayush-AGT on severity of dandruff and quality of life is demonstrated in Table 2.

At baseline, flaking of scalp (98.6%), hairfall (93.7%), itching (90.2%) and dryness of scalp (88.1%) were the symptoms recorded in the study

Table 1 — Baseline characteristics of the participants

Baseline Characteristics (n = 143)			n (%)
Age: Mean ± SD	29.29±8.545(#)		
Gender	Male		54 (37.8%)
	Female		89 (62.2%)
Educational Status	Illiterate		1 (0.7%)
	Primary School Certificate		8 (5.6%)
	SSC (X)		7 (4.9%)
	HSC (XII)		12 (8.4%)
	Graduate		78 (54.5%)
	Post Graduate		37 (25.9%)
Occupation	Desk work		44 (30.8%)
	Field work		26 (18.2%)
	House wife		21 (14.7%)
	Student		40 (28.0%)
	Others		12 (8.4%)
Socio-economic status	Above Poverty Line		128 (89.5%)
	Below Poverty Line		15 (10.5%)
Religion	Hindu		140 (97.9%)
	Muslim		2 (1.4%)
	Christian		1 (0.7%)
Domicile	Urban		126 (88.1%)
	Semi-urban		10 (7.0%)
	Rural		7 (4.9%)
Type of Prakriti	*Vataja*		2 (1.4%)
	Pittaja		1 (0.7%)
	Kaphaja		23 (16.1%)
	Vata-Pittaja		32 (22.4%)
	Vata-Kaphaja		44 (30.8%)
	Pitta-Kaphaja		41 (28.7%)
History of Present Complaints	Onset	Acute	71 (49.7%)
		Chronic	72 (50.3%)
	Aggravating Factors	Yes	67 (46.9%)
		No	76 (53.1%)
Dietary Habits	Vegetarian		53 (37.1%)
	Non-vegetarian		30 (21.0%)
	Mixed		60 (42.0%)
Addictions	Smoking		7 (4.9%)
	Alcohol		3 (0.7%)
	Tobacco (non-smoking)		2 (1.4%)
	None		131 (91.6%)
Frequency of Head Bath	Daily		7 (4.9%)
	3-4 times per week		70 (49.0%)
	Weekly once		44 (30.8%)
	No specific pattern		22 (15.4%)
Application of Oil in Hair	Daily		8 (5.6%)
	3-4 times per week		55 (38.5%)
	Weekly once		57 (39.8%)
	Never		9 (6.3%)
Type of Hair oil used	Sesame Oil		5 (3.5%)
	Coconut Oil		93 (65.0%)
	Medicated Oil (Traditional)		13 (9.1%)
	Others (Other oils available in market)		32 (22.4%)
Use of Hair dye	No		133 (93.0%)
	Yes		10 (7.0%)
Use of Shampoo	No		6 (4.2%)
	Yes		137 (95.8%)
Use of Hair Serum/Gels	No		126 (88.1%)
	Yes		17 (11.9%)

Values are reported as n (%)
Value is reported as mean ± standard deviation

participants. Detailed data presented in Table 3 illustrates the progressive amelioration of symptoms, affirming the consistent positive impact of the intervention on dandruff severity and associated discomfort. The findings of this study demonstrate a notable improvement in all assessed symptoms of dandruff over subsequent follow-ups, with statistically significant results ($p<0.001$), indicative of the therapeutic efficacy of Ayush-AGT lotion. Laboratory assessments, as outlined in Table 4, remained consistently within reference ranges, suggesting the safety of Ayush-AGT lotion. No treatment emergent adverse effects were reported by any participants during the study duration.

The compliance rate among participants using Ayush-AGT lotion, recorded through self-reported compliance forms and assessment of returned empty bottles, was recorded as 99.89% on day 30. This level

Table 2 — Therapeutic effect of Ayush AGT on disease severity and quality of life

Scores	Baseline	15th day	30th day	45th day	p-value
ASFS Score	15.70±4.380	9.27±4.486	5.41±3.979	4.80±4.103	<0.001 (*)
QASS Score	12.78±6.084	7.82±4.816	4.11±3.315	3.33±3.224	<0.001 (*)
DLQI Score	7.06±3.923	4.27±3.074	2.18±2.013	1.85±1.879	<0.001 (*)

Values are reported as Mean ± SD
p-value computed using Repeated Measure ANOVA
(*) A p-value of <0.05 has been considered as significant

Table 3 — Therapeutic effect of Ayush AGT on clinical symptoms of disease

Chief Complaints (n = 143)	Baseline	15th day	30th day	45th day	p-value
Flaking of Scalp (*Kesha Bhumi Prapatana*)	141 (98.6%)	132 (92.3%)	71 (49.7%)	65 (45.5%)	<0.001 (*)
Itching in the Scalp (*Kandu*)	129 (90.2%)	98 (68.5%)	41 (28.7%)	52 (36.4%)	<0.001 (*)
Dryness of scalp with tendency to flakes on scratching (*Keshabhumi Rukshata*)	126 (88.1%)	114 (79.7%)	77 (53.8%)	69 (48.3%)	<0.001 (*)
Hair fall (*Keshachyuti*)	134 (93.7%)	122 (85.3%)	104 (72.7%)	92 (64.3%)	<0.001 (*)

Values are reported as n (%)
p-value compared using Cochrane-Q test
(*) A p-value of <0.05 has been considered as significant

Table 4 — Effect of Ayush-AGT on laboratory parameters

Lab Investigations	Baseline	30th day	p-value
Hemoglobin	13.11±1.852	12.99±1.761	0.108
T.L.C	7064.37±1877.809	7036.40±1896.304	0.871
E.S.R mm at the end of 1st hour	16.31±12.577	17.05±12.548	0.479
D.L.C			
N	56.85±9.130	58.02±7.944	0.089
E	4.80±12.895	4.07±6.757	0.494
B	0.61±0.972	0.67±0.927	0.190
L	32.51±7.475	31.87±7.902	0.379
M	5.93±3.349	6.33±6.802	0.494
Blood Sugar Fasting	86.54±9.573	88.33±9.257	0.024
Blood Urea	20.45±8.029	19.89±5.531	0.429
Serum Ceratinine	0.75±0.424	0.72±0.243	0.457
Serum Uric Acid	4.52±1.633	4.82±3.516	0.307
S.G.O.T (A.S.T)	20.75±7.725	19.95±7.812	0.236
S.G.P.T (A.L.T)	21.24±13.045	21.59±14.492	0.732
Total Protein	7.21±0.428	7.25±0.462	0.222
S. Albumin	4.40±0.435	4.41±0.426	0.758
S. Globulin	2.81±0.396	2.84±0.398	0.255
A/G Ratio	1.61±0.338	1.59±0.330	0.431
Serum Total Bilirubin	0.56±0.324	0.56±0.314	0.711
Conjugated Bilirubin	0.18±0.117	0.19±0.118	0.675
Unconjugated Bilirubin	0.42±0.573	0.38±0.234	0.400
Serum Alkaline Phosphatase	79.83±23.373	77.80±23.095	0.310

Values are reported as mean ± standard deviation and p-value compared using Paired Sample t-test. A p-value of <0.05 has been considered as significant

of adherence underscores the excellent tolerability of Ayush AGT. The remarkable compliance observed suggests that Ayush-AGT lotion can be safely utilized on an alternate-day basis continuously for a period of 30 days without inducing adverse effects or intolerability.

Discussion

The study demonstrates the therapeutic efficacy of Ayush-AGT in reducing the severity of dandruff as elicited through statistically significant reduction in ASFS score and QASS score. The significant decrease in Dermatology Life Quality Index (DLQI) values observed throughout the study period strongly suggests an improvement in the quality of life among participants using Ayush AGT lotion for dandruff management. The progressive reduction in DLQI values suggests that as dandruff symptoms alleviated with Ayush AGT lotion, participants experienced fewer negative impacts on various aspects of their lives, such as emotional well-being, daily activities, and social interactions. These findings highlight not only the therapeutic efficacy of Ayush AGT lotion in managing dandruff but also its broader positive impact on enhancing the quality of life for individuals affected by this condition. It is worth noting that a sustained remissive effect till day 45 was also observed after the use of Ayush-AGT for 30 days. The study findings highlight the exemplary safety and tolerability profile of Ayush-AGT lotion, as evidenced by the absence of any reported adverse effects among participants throughout the 30-day period, despite its alternate-day use. The good compliance observed in the study underscores the excellent tolerability of the lotion under the prescribed regimen. Such high compliance rates not only attest to the absence of significant discomfort or adverse reactions but also emphasize the favourable acceptance by users.

Dandruff is a prevalent condition yet a cause of serious social and emotional distress. There is an array of medicines in the form of shampoos, lotions, oils, and pastes with ingredients ranging from chemical substances to herbal substances that boast different types of benefits in the market. The preference for the public to use herbal substances for cosmetic purposes has also resulted in the surge of research and product development in Ayurveda-based anti-dandruff products. Owing to a diverse range of etio-pathological and triggering factors such as skin surface fungal colonization, sebaceous secretion, individual susceptibility, stress, anxiety, and the interaction of these factors, dandruff persist for a long time or repeatedly recurs. Treatment for dandruff mainly focuses on clearing the symptoms of the disease, such as flaking, itching, inflammation, preventing its recurrence, and maintaining a normal microenvironment for hair.

Curcuma longa L. (turmeric) is a medicinal plant with various pharmaceutical activities, and its use as a skincare product has been reported from time immemorial[10]. Topically, turmeric is reported to have anti-bacterial and anti-inflammatory activity and has been used as a paste for skin eruptions and infections. Curcumin has been shown to down-regulate inflammatory targets and inhibits many inflammatory cytokines, including TNF-α, interleukin-1, -2, -6, -8, and -12[11]. It has also been reported that curcumin regulates nuclear factor kappa B (NF-κB), which is implicated to have a contributory role in many skin diseases characterized by inflammation, such as psoriasis and atopic dermatitis[12,13]. This mechanism could positively affect the inflammatory process that causes flaking or scaling of the scalp in dandruff[14].

Aloe vera (*Aloe barbadensis* Miller), has been used extensively for its pharmacological and cosmetic applications. It is used traditionally to heal wounds, relieve itching and swelling. Results from *in-vitro* studies reveal that aloesin, aloin, and emodin in Aloevera exert a protective action on the skin through the anti-oxidant and anti-inflammatory mechanisms[15]. *A. Barbadensis* is extensively used in producing lotions, soaps, shampoos, creams, and facial cleansers due to its unique properties[16]. The use of aloe-based shampoo helps in hair regeneration, strengthens the hair follicles, prevents hair loss, and stimulates hair growth[17]. Aloe is reported to stimulate fibroblast which produces the collagen and elastin fibers making the skin more elastic and less wrinkled. It also has cohesive effects on the superficial flaking epidermal cells by sticking them together, which softens the skin[18]. Topical Aloe vera therapy is reported to be well tolerated, with no significant adverse drug-related symptoms[19].

Both turmeric and aloe are widely recognized household remedies renowned for their therapeutic properties in managing various skin conditions. Their historical use and well-documented tolerability rendered them ideal candidates for inclusion in the novel formulation to maintain a healthy scalp hair

microenvironment and hence used for the development of an herbal lotion to control the symptoms of dandruff like flaking, inflammation, itching etc.

The findings of this study underscore the therapeutic efficacy of Ayush-AGT lotion in dandruff management, presenting a promising alternative to conventional anti-dandruff products that is sometimes associated with adverse events such as hair fall and cutaneous allergies, Ayush-AGT lotion emerges as a viable therapeutic option, offering both efficacy and safety in addressing the challenges posed by dandruff, without compromising on skin health or overall well-being.

Conclusion

The findings of the study provide compelling evidence of the therapeutic, safety and tolerability profile of the herbal lotion, Ayush-AGT in mild to moderate dandruff. Thereby, offering a promising solution for people who prefer safer herbal choice for control of flaking, and itching in all types of dandruff. The sustained improvement beyond the intervention period underscores the impact of Ayush-AGT lotion in managing dandruff, as it demonstrates a lasting effect even after discontinuation of treatment. The adherence observed in the study bolsters confidence in the lotion's tolerability profile, indicating its suitability for sustained and uninterrupted use in effectively managing dandruff.

Limitations

Since the study was conducted as an exploratory phase II, to provide preliminary evidence demonstrating that Ayush-AGT has the potential to produce the desired therapeutic effect in dandruff, the study was conducted as a single arm study without a control group. This limits the ability to compare outcomes with alternative treatments or placebo. Consequently, this may restrict the generalizability of the findings and the ability to conclusively attribute observed improvements solely on Ayush-AGT. Despite this limitation, the study provides valuable preliminary evidence regarding the potential efficacy of Ayush-AGT lotion, serving as a foundation for future research endeavors.

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Conflict of Interest

All authors involved in this work are affiliated with the Central Council for Research in Ayurvedic Sciences (CCRAS), the organization that self-funded the conduct of the study at CCRAS institutions.

Author Contributions

SPG, KK, TC, SD, AA, RN, DSH contributed in Investigation, Data collection and manuscript review. SK contributed to the conceptualization, methodology, and protocol review. SJ was involved in protocol writing and drafted the manuscript. BSS contributed in intervention procurement and article review. SK contributed in Data collection and manuscript review. RR, RS conducted the statistical planning, formal analysis and article review. BCS reviewed the protocol and provided overall supervision. TM contributed to the conceptualization and design. NS contributed in conceptualization, Project administration and article review. KSD contributed in project administration.

Ethics Approval

The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and the guidelines of the Indian Council of Medical Research (ICMR) for biomedical research involving human participants. The trial protocol was reviewed and approved by the IEC of all study sites.

Trial Registration Number

The clinical study was registered prospectively with ID CTRI/2020/03/024092

Informed Consent

Written informed consent was obtained from all participants prior to their enrollment in the study. Participants were informed about the study objectives,

procedures, potential risks and benefits, and their right to withdraw at any time without any consequence to their standard care. The confidentiality of participant data was maintained throughout the study.

Data Availability

The data generated and analyzed during this study are not publicly available due to institutional and ethical restrictions. However, de-identified participant data and relevant study materials (such as the protocol and statistical analysis plan) may be made available from the corresponding author upon reasonable request, subject to institutional approvals and data sharing agreements.

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