ORIGINAL RESEARCH PAPER
Volume - 15 | Issue - 11 | November - 2026 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

EFFICACY AND SAFEFFICACY OF AMRADI SHAMPOO IN MODERATE PITYRIASIS CAPITIS – A RANDOMIZED CONTROLLED TRIAL

Ayurveda

Anchu Thomas* PG Scholar, Department of Dravyagunavigyan, Govt. Ayurveda College, Thiruvananthapuram. Pin code – 695001, Kerala, India*Corresponding Author

Dr. A Shahul Hameed MD (Ay), Retd. Professor & HOD Department of Dravyagunavigyan, Government Ayurveda College, Thiruvananthapuram, Pin code – 695001, Kerala, India

Dr. Indulekha V C Associate Professor, Department of Dravyagunavigyan, Govt. Ayurveda College, Thiruvananthapuram. Pin code – 695001, Kerala, India

ABSTRACT

Background: Pityriasis capitis (dandruff/Darunaka) is a common scalp disorder with scaling and itching. As conventional treatments may cause recurrence and adverse effects on prolonged use, so safer herbal alternatives are needed. Based on the recommendation of Sarngadhara Samhitha regarding the use of Amrabeeja(Mangifera indica) and Harithaki (Terminalia chebula) for managing Darunaka, Amradi shampoo (AS) was formulated and compared with 1% ketoconazole shampoo (KS) in moderate Pityriasis capitis. Objectives: Present Study aimed to evaluate the efficacy and safety of Amradi Shampoo in moderate Pityriasis capitis. **Materials & Methods:** AS was prepared using aqueous extracts of Amrabeeja and Harithaki (3:2) with suitable shampoo base ingredients. In a randomized comparative study, 60 patients (18–60 years; ASFS ≥25) were randomly allocated to AS or KS groups (30 each). Participants used 100 ml of the assigned shampoo twice weekly for 30 days. Efficacy was assessed using Adherent Scalp Flaking Score (ASFS) and Investigator Global Assessment of Pruritus score (IGAPS), while safety was evaluated using Treatment-emergent adverse events (TEAE) scores. **Results and Discussion:** AS showed acceptable quality, stability, permissible microbial and heavy metal limits, one-year shelf life, and no irritation. Both AS and KS significantly reduced scaling and itching ($p < 0.001$). Mean ASFS decreased from 28.87 ± 2.64 to 20.00 ± 3.13 in AS and from 28.47 ± 2.89 to 19.70 ± 2.93 in KS, with all participants improving from moderate to mild severity. IGAPS scores also improved significantly ($p < 0.01$). No significant difference was observed between groups. AS showed better tolerability, with no adverse effects on TEAE assessment.**Conclusion:** Amradi shampoo is effective and safe in the management of moderate Pityriasis capitis.

KEYWORDS

Amradi Shampoo, Pityriasis Capitis, Dandruff, Darunaka, ASFS, IGAPS, TEAE.

INTRODUCTION

Pityriasis capitis, also referred to as dandruff, is a frequently occurring scalp disorder marked mainly by scalp flaking and itching with out obvious inflammation.[1] The prevalence of Pityriasis capitis is reported to be 60.1% in South Asia, approximately 50% worldwide, and nearly 70% among Indians.[2]Increased proliferation of the yeast Malassezia spp, excessive sebaceous gland activity, and individual susceptibility are the major contributing factors in its pathogenesis. Malassezia secretes lipases that act on human sebum and break down triglycerides into free fatty acids.[3] These fatty acids penetrate the stratum corneum, leading to inflammation and abnormal keratinization. Diagnostic assessment of Pityriasis capitis is mainly based on clinical evaluation of scaling, pruritus, and minimal inflammation without significant hair loss.It is managed with topical antifungal, keratolytic, and anti-inflammatory formulations. Agents such as ketoconazole, zinc pyrithione, clotrimazole, and selenium sulphide help reduce fungal growth, scaling, and itching.[5] Herbal remedies including tea tree oil, Aloe vera, neem, henna, and rosemary also show anti-dandruff potential.[6] Despite the availability of multiple therapeutic options, issues such as potential side effects, insufficient treatment response, and the high cost of certain medications have increased the demand for complementary and alternative therapies, particularly those derived from natural sources.

In Ayurveda Pityriasis capitis is correlated to *Darunaka,* classified under *Sirokapala rogam* as well as *Kshudra roga* (Head diseases and minor diseases). [7] This condition, presents with *kandu* (itching), *keshachyuthi* (hair fall),*roukshya* (dryness*), swapa* (numbness), and *twaksphutanam* (scaling), of the scalp (FA-4).[8] The primary *doshas* involved are *vata* and *kapha*. The condition can be managed with diet, *Panchakarma* procedures along with some internal medicine, external application of drugs and washing (*kshalanam*).Dandruff affects half of the population in this world. So a good solution must be found to reduce dandruff. Regular use of chemical shampoos can damage hair roots and lead to premature hair fall, greying, scalp dryness, itching, and split ends. To overcome these problems, herbal shampoos are considered a better alternative.

Hence a novel preparation coveniently named as *Amradi* Shampoo (AS) was formulated with *Amrabija* (seed kernel of *Mangifera indica* L.) and *Haritaki* (fruit rind of *Terminalia chebula* Retz.) as the active herbal ingredients, selected based on the classical Ayurvedic reference in *Sarṅgadhara Saṃhita,* which describes their external application (*lepa*) for the management of *Darunaka*. [9] In AS, a total of 5 g of aqueous extracts of seed kernel of *Mangifera indica* L. and fruit rind of *Terminalia chebula* Retz. In a 3:2 ratio, along with sodium lauryl sarcosinate, cocamidopropyl betaine, decyl glucoside, methylcellulose, glycerine, sodium benzoate, and potassium sorbate in the ratio of 6:4:3:1:5:0.25:0.25, respectively. Demineralized water (42 mL) was added to make up the volume to 100 mL of shampoo. 1% ketoconazole shampoo (KS) were used as comparator drug. The antifungal effect of KS had already been proven, and conventional KS contain Sodium Lauryl Sulfate (SLS), and parabens.

A pilot study conducted in ten participants with moderate Pityriasis capitis found that the combination was effective, safe, and caused no irritation to the scalp and hair. Thus to determine the efficacy of the *Amradi* shampoo, a randomized controlled clinical trial was conducted in moderate Pityriasis capitis participants, of the age group 18 to 60 years, and either AS or KS was applied over the scalp twice a week for a period of 30 days and assessed with Adherent scalp flaking score (ASFS), and Investigator Global Assessment of Pruritus score (IGAPS), while safety was evaluated using Treatment Emergent Adverse Event (TEAE) scores.

MATERIALS AND METHODS

Authentication of herbal ingredients - The fruit rind of *Harithaki* (*Terminalia chebula* Retz), and seed kernel of *Amra (Mangiferia indica L.)* were collected. They were authenticated by plant taxonomist. The dried aqueous extracts of these drugs were prepared. Quantitative and qualitative assessment was done as per ICMR (Indian Council of Medical research) guidelines.

Preparation and Standardization of Amradi shampoo

In AS, a total of 5 g of aqueous extracts of seed kernel of *Mangifera indica* L. and fruit rind of *Terminalia chebula* Retz. In a 3:2 ratio, along with sodium lauryl sarcosinate, cocamidopropyl betaine, decyl glucoside, methylcellulose, glycerine, sodium benzoate, and potassium sorbate in the ratio of 6:4:3:1:5:0.25:0.25, respectively. Demineralized water (42 mL) was added to make up the volume to 100 mL of shampoo. The final product was a homogeneous, smooth, and stable herbal shampoo.

The preliminary standardization of *Amradi* shampoo was carried out according to standard procedures. Shampoo regulation is monitored by the "Central Drugs Standard Control Organization under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. AS was standardized by evaluating its organoleptic characteristics, pH, percentage of solids, dirt dispersion, foam ability and stability, viscosity, surface tension, wetting time, cleansing action, solubility, and skin irritancy.

Further evaluation of *Amradi* shampoo included estimation of microbial contamination/load, heavy metal analysis, HPTLC fingerprinting, and Accelerated stability studies for assessment of its quality, safety, and shelf life.

Clinical evaluation

Study design- A prospective, randomized, comparative clinical trial was conducted at the OPD of Dravyagunavijnana, Government Ayurveda College Hospital, Thiruvananthapuram, from June 2024 to October 2025.

Ethical Considerations: The study was registered with the Clinical Trials Registry–India (CTRI/2025/05/086324) on 05/05/2025. It was conducted in accordance with the Declaration of Helsinki (2013) and ICH-GCP E6 (R2) guidelines. Institutional Ethics Committee approval was obtained (IEC No. 694-6/10/2023), and written informed consent was obtained from all participants before study initiation.

Objectives- To determine the efficacy of external application of *Amradi* shampoo, over the scalp twice a week for a period of 30 days is reducing adherent scalp flaking score (ASFS) ,when compared with 1% Ketoconazole shampoo in moderate Pityriasis capitis participants of age group 18 to 60 years, attending the out-patient department of Dravyagunavigyan, Government Ayurveda College, Thiruvananthapuram.

Hypothesis - Null hypothesis: External application of *Amradi* shampoo, is not equally effective in reducing adherent scalp flaking score (ASFS), when Compared with 1% Ketoconazole shampoo in moderate Pityriasis capitis.

Alternate hypothesis: External application of *Amradi* shampoo, is equally effective in reducing adherent scalp flaking score (ASFS) , when compared with 1% Ketoconazole shampoo in moderate Pityriasis capitis.

Inclusion criteria - Participants with Pityriasis capitis - Adherent flaking scalp score is ≥25
at the baseline visit, Age in between 18 to 60 years.

Exclusion criteria - Other concomitant skin diseases of the scalp. History of allergic reaction to shampoos, perfumes or topically applied hair care products. Used antidandruff anti-psoriatic or anti-seborrheic dermatitis shampoos within 2 weeks prior to baseline.

Sample Size - Sample size is 30 in each group with total 60. Therefore 60 Subjects diagnosed with Pityriasis capitis in the age group 18-60 years was to be enrolled and randomly assigned in to two groups as Group 1 and Group 2.

Procedure:

To recruit trial participants they underwent screening process including the participants' demographic profile, a thorough medical history, and a physical and systemic examination. During the first visit (0th day), the participant's ASFS was calculated and the flakes was evaluated by inspection. Eligible participants were provided with either AS or KS which was advised for external application over the scalp, twice in a week, for a period of 30 days. Participants allocation was done at 1:1 ratio using Computer generated random number tables. If they were using any other shampoo till date, the trial drug was given only after 1 week washout period. The participants was offered either Amradi shampoo or Ketoconazole shampoo as per their allocation. The shampoo has to be applied twice in a week for a period of 30 days, as a home scalp washing regimen. The regimen is to apply enough amount of shampoo to their scalp, massage gently and then rinsing with enough quantity of plain water in their home. Participants will be monitored by a phone once in a week. The participants will be evaluated at 0^{th}, and 31^{st} days on the basis of ASFS and IGAPS.

Outcome measures:

The change in ASFS Score, IGAPS from baseline to the end of the study (31 the day).Representative patient photographs were taken at baseline and to the end of the Study. Safety was assessed with TEAE Score and local skin reactions were evaluated at each visit.

Statistical analysis

SSPS software was used for analysing the Data. Normality of continuous data (ASFS scores) was evaluated using the Kolmogorov–Smirnov test and Shapiro–Wilk test, which showed that the data followed a normal distribution. For within-group comparison (before and after treatment), the paired t-test was used. For between-group comparison, the independent samples t-test was applied, along with Levene's test to assess equality of variances.

RESULT AND ANALYSIS

Standardization of AS - Macroscopic and microscopic characters of ingredients of AS with API parameters physicochemical analysis and phytochemical analysis results matches with API parameters and reveals the presence of Alkaloids, Tannins, Flavonoids, Steroids, Saponins and phenols in test.

EVALUATION OF STANDARDIZATION OF AS.

a) Organoleptic Evaluation of AS

Organoleptic characters such as colour, taste, odour, etc of AS was observed and given in the Table No: 1

Table No1: Results of organoleptic evaluation of AS.

SL NO	PARAMETER	AS
1	Appearance	Smooth liquid
2	Colour	Brown
3	Odour	Characteristic
4	Clarity	Turbid , No gritty particle present

b) Physicochemical Evaluation

pH, Determination, Determination of percentage of solids, Dirt dispersion, Foam ability and stability, Viscosity, Surface tension, wetting time etc was shown in the Table No: 2.

Table No: 2 Physicochemical Evaluation of AS

SL.NO	PARAMETER	AS
1.	Ph	5.64
2.	Determination of percentage of Solids	21 %
3.	Dirt dispersion	Light dirt in water
4.	Foam ability and stability	90 ml after 1 minute
5.	Viscosity	2500 cP
6.	Surface Tension	30 dynes/cm
7.	Cleaning Action	Complies
8.	Wetting time	30sec
9.	Water Solubility	Soluble
10.	Ethanol Solubility	Soluble
	Microbial load Analysis of AS	
11.	Total Aerobic Microbial Count	1.2 × 102 CFU/ml
12.	Total Yeast & Mold Count	0.5 × 10^2 CFU/ml
13.	Staphylococcus aureus"	Absent
14.	Escherichia coli"	Absent
15.	Aspergillus niger"	Absent
16.	Pathogen Compliance	Within acceptable limit
17.	Preservative Effectiveness	Moderate (herbal base)
	Heavy metal Analysis	
18.	Hg, Cd, Pb, Ar	With in permissible limits
	HPTLC Analysis.	
19.	Rf values at 254nm	0.006, 0.034,0.127 0.166,0.347,0.644,
	Rf values at 366nm	0.005, 0.035, 0.108 0.131,0.192,0.347
20.	Shelf life	1 year

Skin irritancy test – Patch Test

Skin irritancy test for AS conducted in 10 volunteers after taking written consent and AS applied on the left-hand dorsal surface as per procedure, No skin irritation was noticed in all participants.

Results of HPTLC analysis

HPTLC analysis was carried out using the methanolic extracts of the individual ingredients and the finished formulation of AS. The optimum separation of constituents was achieved using the solvent system Hexane: Ethyl acetate: Formic acid (7 ml: 3 ml: 2 drops) for *Mangifera indica Linn and Terminalia chebula Retz*.In the case of Amradi shampoo, the solvent system Ethyl acetate: Toluene: Methanol: Formic acid:Water in the ratio of 6: 4: 1.5: 0.5: 0.5 was used. A common Rf value around 0.02 observed in all Samples at both wavelengths suggested the presence of common phytochemical constituents derived from the herbal ingredients. Rf values at 254 nm and 366 nm are given in Table No 2.

Shelf life of AS

Shelf life of AS were determined by 3 month stability study and conducted by Ayush approved laboratory. Shelf-life parameters such as physicochemical parameters, microbial load analysis, test for specific pathogens etc were tested. No pathogenic organisms developed during storage. These findings indicate good physicochemical and microbiological stability of the formulation, and based on the accelerated stability study, the formulation may be provisionally assigned a shelf life of one year.

CLINICAL STUDY

The study entitled "Efficacy of *Amradi* shampoo in pityriasis capitis (*darunaka*)" was conducted in outpatient Department of Dravyagunavigyan, Govt. Ayurveda Hospital, Thiruvananthapuram. A total of 70 individuals screened and 65 satisfied the inclusion criteria. From these, 2 participants were not willing to take part the study. The remaining 63 participant, who gave consent were randomized into trial and control groups. In which 31 assigned to the trial group and 32 to the control group. During the study, one participant from the AS group and two participants from the KS group could not attend the scheduled assessment due to travelling difficulties. Ultimately, 60 participants that is 30 participants in each group was received either AS or KS medications, completed the 30th-day intervention, their data were analysed statistically. Consort flow chart is shown in Figure No: 1.

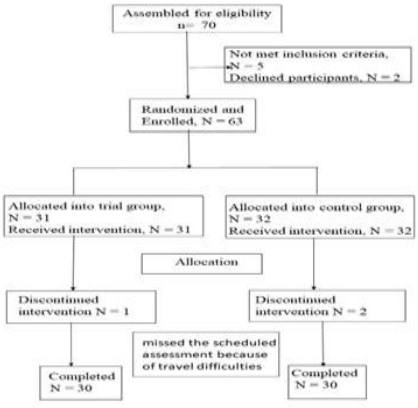

Figure No: 1 Consort diagram.

Analysis of sociodemographic characteristics revealed that the majority of participants belonged to the 18–30 years age group (61.6%), Female participants (68.3%) were more compared to males (31.7%). Most participants were graduates (65%), belonged to rural areas (76.7%), and were from middle socioeconomic status (68.4%). Most participants had regular dietary habits, normal bowel habits, sound sleep, and no significant mental stress. More than half of the participants had no history of allergy.

Scalp and Hair related parameters.

Scalp and hair realted parameters of the participants are as shown in the Table No: 3, Both the groups are homogenous and comparable with respect to all factors minimizing potential confounding.

Table No: 3 Scalp and Hair related parameters.

Scalp and Hair related parameters	Category	Ketoconazole Shampoo Number (KS - %)	Amradi Shampoo Number (AS - %	Total Number	P – value
Scalp Condition	Oily	17 (56.7%)	21(70%)	38(63.3%)	0.284
	Dry	13(43.3%)	9(30%)	22(36.7%)	
Hair Distribution	Uneven	4 (13.3%)	4(13.3%)	8 (13.3%)	1.00
	Even	26(86.7%)	26(86.7%)	52(86.7%)	
Hair Thickness	Normal	22(73.3%)	25(83.3%)	47(78.3%)	0.347
	Thinning	8(26.7%)	5(16.7%)	13(21.7%)	
Hair fall	Nil	16(53.3%)	9(30%)	25(41.7%	0.067
	Present	14(46.7%)	21(70%)	35 (58.3%)	

No statistically significant differences ($p > 0.05$) were observed between the groups at baseline with respect to socio-demographic, dietary, lifestyle, and scalp and hair-related parameters.

Analysis of ASFS.

The pre and post outcome parameters obtained in both the groups were initially subjected to normality test. The results of normality test for KS and AS on ASFS as shown in Table No: 4

Table No: 4 Normality Test for KS and AS on ASFS.

Group		Kolmogorov-Smirnov			Shapiro-Wilk		
		Statistic	Df	p-value	Statistic	Df	p-value
Control (KS)	ASFS 0th day	.104	30	.200*	.970	30	.543
	ASFS 31th day	.119	30	.187	.896	30	.053
Trial(AS)	ASFS 0th day	.127	30	.200*	.944	30	.119
	ASFS 31th day	.135	30	.164	.911	30	.068

Comparison of ASFS before and after (Paired t-test)

Paired t-test was used to evaluate the treatment efficacy in both KS and AS groups by comparing ASFS scores at baseline (0th day) and post-treatment (31st day). paired t-test analysis demonstrated a significant reduction in ASFS scores after treatment in both groups ($p < 0.001$). In the control group, the mean ASFS score reduced from 28.47± 2.89 to 19.70 ± 2.93, with a mean reduction of 8.77 points. Similarly, in the trial group, the mean ASFS score decreased from 28.87 ± 2.64 to 20.00 ± 3.13, with a mean reduction of 8.87 points.Comparison of ASFS in Control and trial group before and after as shown in the Table No: 5, 6.

Table No: 5 Control Group ASFS before (0th day) and after (31st day).

ASFS	N	Mean	SD	SE of Mean	t-value	Df	p-value
0th day	30	28.47	2.89	.53	28.31	29	<.001
31th day	30	19.70	2.93	.53			

Table No: 6 Trial Group ASFS before and after treatment.

ASFS	N	Mean	SD	SE of Mean	t-value	Df	p-value
0th day	30	28.87	2.64	.48	28.30	29	<.001
31th day	30	20.00	3.13	.57			

An independent samples t-test was used to compare ASFS scores between the control and trial groups at baseline and on the 31st day. The results showed no statistically significant difference at baseline ($t = 0.561$, $df = 58$, $p = 0.577$) and on the 31st day ($t = -0.384$, $df = 58$, $p = 0.703$) ($p > 0.05$), indicating that both groups remained comparable at both time points.

Analysis of IGAPS in trial and control group.

IGAPS as shown in the Table No: 7, 8

Table No: 7 Analysis of IGAPS in Control and Trial groups.

Group	Assessment	Mean	SD	Wilcoxon Signed Rank Z value	p value
Control	Before	1.97	0.61	- 5.12	< 0.01
	After	0.80	0.41		
Trial	Before	1.83	0.59	-5.26	< 0.01
	After	0.73	0.45		

Table No: 8 IGPAS Assessment

Group	Assessment	No Pruritus n (%)	Mild discomfort	Appreciable discomfort	Extreme Discomfort

Control	Before	0	8 (26.7%)	19(63.3%)	3 (10%)
	After	8 (26.7%)	22(73.3%)	0	0
Trial	Before	0	6 (20%)	19(63.3%)	5 (16.7%)
	After	6 (20%)	24(80%)	0	0

Analysis of safety of treatment with respect to TEAE score.
Safety of treatment with respect to TEAE score and LSR score is shown in table No: 9

Table No: 9 Safety of treatment with respect to TEAE score and LSR score

Category	AS (n=30)	KS (n = 30)	Grade/Score Interpretation
TEAE Score.	No adverse effects reported	Mild headache in 2 participants (6.7%) The symptoms had a sudden onset and subsided after a short duration during KS use.	AS: Grade 0 KS: Grade 1 (mild).
LSR Score.	No local skin reactions observed	Scalp and hair dryness in 5 participants (16.7%)	AS: Grade 0 KS: Grade 1 (mild)

DISCUSSION

Pityriasis capitis or dandruff, is a widely occurring dermatological disorder that affects almost half of the global population at some point during their lifetime.[1] Dandruff is characterized by scalp flaking, scaling, and itching, mainly associated with *Malassezia*, sebum, and individual susceptibility.[2],[3] Diagnosis is mainly clinical, supported by dermatoscopy when required. Current management includes antifungal and anti-inflammatory treatments, mainly medicated shampoos. Regular scalp hygiene and healthy lifestyle practices help prevent recurrence.[4]

A considerable number of in vitro, in vivo, and clinical studies have demonstrated the efficacy of herbal formulations in the management of Pityriasis capitis. Many of them have not clinically evaluated with trials. Clinical trials are helps to assess safety, efficacy, side effects and outcome evaluation etc.

In Sarngadhara Samhitha, the context of Darunaka chikitsa a lepa (external application) is mentioned which contains *Amrabeeja (seed kernel of Mangifera indica L.)* and *Harithaki (fruit rind of Terminalia chebula Retz.*).[9] Based on their therapeutic properties, these two drugs were formulated into a shampoo preparation, *Amradi* Shampoo (AS). In AS, 5 g of dried aqueous extracts of *Amrabeeja* and *Harithaki* were blended in a ratio of 3:2 along with sodium lauryl sarcosinate, cocamidopropyl betaine, decyl glucoside, methylcellulose, glycerine, sodium benzoate, and potassium sorbate in the proportions of 6:4:3:1:5:0.25:0.25 respectively. Demineralized water (42 ml) was added to adjust the final volume to 100 mL of shampoo. The *Ruksha guna of these drugs* helps to reduce excessive scalp oiliness, while their *Kaphahara* property assists in correcting the vitiated *doshas* involved in dandruff pathology. The *krimighna* property of *Amrabeeja* helps to inhibit dandruff-causing microorganisms, while the *kandughna* property of *Harithaki* relieves itching of the scalp.Therefore, considering these common pharmacological properties, *Amrabeeja* and *Harithaki* were selected for the formulation of the study drug.

The active ingredients present in these drugs help reduce dandruff through their antifungal, antibacterial, and antioxidant actions, thereby controlling scalp infection and improving scalp health. They also help eliminate the microorganisms responsible for dandruff.The standardization of individual drugs of Amradi shampoo was carried out as per the guidelines mentioned by CCRAS (Central Council for research in ayurvedic sciences for rawplant materials). The authenticity of each ingredient herb was confirmed by pharmacognostic, physicochemical, and phytochemical assessment and compared with established standards in the Ayurvedic Pharmacopoeia of India. Macroscopic, microscopic, and powder microscopic examinations were performed, and the observed characters matched with the existing literature, revealing the purity and genuineness of market samples. Physicochemical evaluation was carried out to assess the quality and purity of the raw drugs.

In the preparation of AS, Aqueous extraction was selected because it effectively extracts water-soluble phytoconstituents, provides better safety, eco-friendliness, and compatibility with herbal shampoo formulations. *Harithaki* showed a higher extractive value, and the ratio of *Amra* and *Harithaki* was optimized to 3:2 to balance anti-dandruff activity with scalp moisturization and minimize excessive dryness due to the astringent nature of *Harithaki.* The formulation incorporated mild surfactants such as Sodium Lauryl Sarcosinate, Decyl Glucoside, and Cocamidopropyl Betaine (6:3:4 ml), which provide effective cleansing and foaming with comparatively less scalp irritation and dryness. Decyl Glucoside, being plant-derived and biodegradable, also enhances scalp compatibility. Cocamidopropyl Betaine additionally acts as a conditioning agent and helps reduce the harshness of other surfactants. Conventional shampoos commonly contain harsh surfactants such as Sodium Lauryl Sulfate (SLS) and Sodium Laureth Sulfate (SLES), along with synthetic fragrances, parabens, silicones, and artificial preservatives.

Studies have reported adverse effects associated with conventional shampoo ingredients. Gavazzoni Dias et al. reported that strong anionic surfactants such as Sodium Lauryl Sulfate may cause scalp dryness, irritation, increased hair friction, and hair damage on prolonged use. Hafeez and Maibach reported that parabens used as preservatives in cosmetic products may be associated with allergic contact dermatitis and skin sensitivity.[11] [12] Glycerine (5 ml) was included as a humectant to retain moisture and prevent dryness of the scalp and hair. Methylcellulose (1g) a semi-synthetic cellulose derivative improved the viscosity and consistency of the formulation, ensuring better application and stability. Sodium benzoate and potassium sorbate (0.25g each) were added as preservatives to inhibit microbial growth and improve shelf life. [13]

The control formulation selected for comparison was 1% Ketoconazole shampoo (KS), which is a widely accepted standard anti-dandruff shampoo. In vitro studies have shown that agents such as Ketoconazole, ZPT, selenium sulfide and piroctone olamine have good activity against human strains of Malassezia spp.[14] Content of KS was Ketoconazole 1% w/v as the active ingredient along with a shampoo base, which generally includes sodium lauryl ether sulfate, cocamidopropyl betaine, sodium chloride, methyl paraben and propyl paraben, fragrance, colour agents, and purified water. [15] Sulfats and paraben causes adverse reaction for users. Standardization of Amradi Shampoo (AS) included physicochemical, microbiological, heavy metal, HPTLC, irritancy, and stability studies. The formulation showed acceptable physicochemical properties, including pH 5.64, viscosity 2500 cP, and satisfactory cleansing and foaming characteristics, with no skin irritation. Microbial analysis confirmed acceptable microbial quality, with *Aspergillus niger* remaining within permissible limits. Heavy metal analysis showed mercury, arsenic, cadmium, and lead within API permissible limits. HPTLC fingerprinting demonstrated characteristic phytochemical profiles, supporting the identity and quality control of AS. Accelerated stability testing showed minimal changes over three months, supporting good stability and a provisional shelf life of one year.

In clinical study a randomized controlled trial was conducted among 18–60-year-old participants with moderate Pityriasis capitis (ASFS ≥25). Participants were randomized equally to AS or 1% Ketoconazole shampoo, applied twice weekly for 30 days, and assessed on days 0 and 31 using ASFS and IGAPS. Analysis of Adherent Scalp Flaking Score (ASFS) was used to assess scalp health in patients with Pityriasis capitis. Normality testing showed that the data were normally distributed in both groups, confirming baseline comparability. So paired t-test analysis demonstrated a significant reduction in ASFS scores after treatment in both groups ($p < 0.001$). In the control group, the mean ASFS score reduced from 28.47 ± 2.89 to 19.70 ± 2.93, with a mean reduction of 8.77 points. Similarly, in the trial group, the mean ASFS score decreased from 28.87 ± 2.64 to 20.00 ± 3.13, with a mean reduction of 8.87 points. Independent sample t-test analysis showed no statistically significant difference between the groups at baseline and post-treatment ($p > 0.05$), indicating that both treatments were equally effective. All participants with moderate Pityriasis capitis at baseline showed improvement to mild Pityriasis capitis after treatment, as evidenced by the reduction in ASFS scores in both groups. In IGAPS showed a marked reduction in pruritus severity in both groups. The trial group showed slightly higher percentage reduction (60.1%) compared to the control group (59.4%).These findings indicate that both formulations were effective in relieving itching and scalp discomfort in Pityriasis capitis.Safety was assessed by TEAE (Treatment-emergent adverse events) score and LSR (local skin

reactions) score. During the study, AS showed better tolerability with no adverse effects, Whereas KS users reported mild headache (6.7%) and local skin reactions (LSR) such as dryness of the scalp and hair (16.7%).These side effects may reduce patient comfort and long-term compliance.

Hence we justify AS as a safer, better-tolerated, and potentially compliance-improving alternative to KS. Thus, the combined action of *Amrabeeja* and *Harithaki* in *Amradi* Shampoo may help break the pathogenesis of *Darunaka* by reducing Kapha-induced oiliness (Oily scalp) and scalp scaling, pacifying Vata-related dryness and itching, controlling fungal colonization (*Krimi*), reducing oxidative stress and inflammation, and improving scalp health through *Twakprasadana* and *Vranaropana* actions. The synergistic antifungal, antimicrobial, antioxidant, anti-inflammatory, sebum-regulating, cleansing, and healing activities of these phytoconstituents may be responsible for the significant reduction in Pityriasis capitis severity observed in the present study.

CONCLUSION

Thus, the study concludes that AS is effective and safe in the management of moderate Pityriasis capitis.External application of Amradi shampoo over the scalp twice weekly for a period of 30 days is equally effective in reducing the Adherent Scalp Flaking Score (ASFS) when compared with 1% Ketoconazole shampoo in participants with moderate Pityriasis capitis.

REFFRENCES

1. Bhattacharyya A, Jain N, Prasad S, Jain S, Yadav V, Ghosh S, et al. Evaluation of therapeutic potential of VB-001, a leave-on formulation, for the treatment of moderate adherent dandruff. BMC Dermatology. 2017; 17:5.
2. Limbu SL, Pura TSO, Harries M, Wikramanayake TC, Miteva M, Bhogal RK, et al. A folliculocentric perspective of Pityriasis capitis pathogenesis: could a troublesome condition be caused by changes to a natural secretory mechanism? Bioessays. 2021; 43(10):e2100005.
3. Sadhasivam S, Garkhal K, Singh H, Yadav V, Chawrai S, Ramnane M, et al. Newly developed anti-Pityriasis capitis regimen, VB-3222, delivers enhanced sensorial and effective therapeutic benefits against moderate adherent Pityriasis capitis. Clin Cosmet Investig Dermatol. 2020; 13:187-195.
4. Kumari KMU, Yadav NP, Luqman S. Promising essential oils/plant extracts in the prevention and treatment of Pityriasis capitis pathogenesis. Curr Top Med Chem. 2022; 22(13):1104-1133.
5. Elwyn A, Govindaraj S. Study of plant-based cosmeceuticals and skin care. S Afr J Bot. 2023; 158:429-442.
6. Bacon RA, Mizoguchi H, Schwartz JR. Assessing therapeutic effectiveness of scalp treatments for dandruff and dermatitis, part 1: a reliable and relevant method based on the adherent scalp flaking score (ASFS). J Dermatolog Treat. 2014; 25(3):232-236.
7. Murthy KRS. English translation of Ashtanga Hridaya. Vol. 3. Reprint ed. Varanasi: Chowkhamba Krishnadas Academy; 2012. Uttarasthana, Sirorogavijnaneeyam, Chapter 23, Sloka 23:222.
8. Sheshagiri S. NAMASTE Portal: a standard reference repository for Ayurvedic terminologies. J Indian Syst Med. 2021. Darunaka (FA-4): Pityriasis capitis (TM2). CCRAS.9.Sarngadhara Sarngadhara Samhita. Madhyama Khanda, Lepamurdhathailadividhi, verse 3.11.20.
10. Central Council for Research in Ayurvedic Sciences. Guidelines for development of Ayurvedic formulations. Vol. 1. New Delhi: Ministry of AYUSH, Government of India; 2018.
11. Gavazzoni Dias MFR. Hair cosmetics: an overview. Int J Trichology. 2015; 7(1):2-15.
12. Hafeez F, Maibach H. An overview of parabens and allergic contact dermatitis. Skin Therapy Lett. 2013; 18(5):5-7.
13. Hammer KA, Carson CF, Riley TV. In vitro activities of ketoconazole, econazole, miconazole, and Melaleuca alternifolia (tea tree) oil is against Malassezia species. Antimicrob Agents Chemother. 2000; 44(2):467-469.
14. Barak-Shinar D, Green LJ. Scalp seborrheic dermatitis and dandruff therapy using a shampoo-based treatment. J Clin Aesthet Dermatol. 2018; 11(1):26-30.
15. Govindaraghavan S, Sucher NJ. Quality assessment of medicinal herbs and their extracts: criteria and prerequisites for consistent safety and efficacy of herbal medicines. Epilepsy Behav. 2015; 52:363-371.