Pharmaceutical Development, Standardization and Clinical Evaluation of Efficacy of a Polyherbal Hair-Pack and Hair Gel in Dandruff Control

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Authors’ contributions

This work was carried out in collaboration among all authors. New formulation of Hair pack will be designed which will prove beneficial in curing dandruff and its associated symptoms. A cost effective cosmetic product will be provided to the society. All authors read and approved the final manuscript.

ABSTRACT

Introduction: Dandruff is a commonly found hair problem affecting all age groups with high recurrence and is considered a social stigma. In Ayurved it is compared with Darunak falling under the category of kshudraragadhikar and is caused due to the vitiation of vaat and kapha. Traditionally the treatment comprises of application of oil, steaming, applying packs, washing of hair etc. According to modern science dandruff is a non-treatable disease condition which is

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1. INTRODUCTION

Dandruff is a commonly observed affliction that affects most of the adults across regions, ethnicities, and societies. The most vulnerable age group is in the post-pubertal stage [1] (aged mostly between 18-60 years). Dandruff not only affects the aesthetics by rendering the hair (and the scalp) dry and lustreless, but also is accompanied by itching of the scalp. With respect to seasonal effect, it has been established that the dandruff severity can accentuate during winters [2]. It has also been observed that those afflicted with dandruff are prone to losing hair faster than those without dandruff. It is observed in a two day study that dandruff afflicted individuals lost at least twice the hair count compared to those without the disorder [3].

Further, the detergent treatment has temporary effect, and the subject may face recurrence of the dandruff. The main reason for recurrence is that the exact cause for dandruff formation has not been established [4]. As such, the treatment is symptomatic, temporal and aimed mainly at providing temporary relief from scaling and itching though generally, there is no inflammation associated with dandruff. Consequently, the conventional treatment is mostly cosmetic in nature. The sensitivity of sebum rich human scalp to androgen is recorded in literature [3,5]. The formation of sebum coinciding with the onset of puberty explains the relation of age with dandruff formation.

The lack of holistic approach to the disorder/disease arises from the fact that the underlying causes are yet to be validated. In times of lifestyles seeking instant gratification and relief, a medicine to be ingested requiring no preparation time, a hair pack to be applied as infrequently as possible with maximum benefits or as a gel that provides lasting relief upon usage of shorter durations is the need of hour. Hence formulations that are convenient to use, are available in plenty, and are hence cost-effective is being sought earnestly.

Recent literature points to the fact that many naturopathic agents, both independently and in combination help in antidandruff activity [6-7]. The recognition of the results of herbal formulations is indicative of the validity of the Ayurvedic methodology and approach to dandruff treatment. Further, literature also validates the finding that naturopathic treatment has been found to be scientifically validated in both in-vitro and in-vivo research studies [8–10].

Ayurveda the holistic science that advises on maintaining overall health and building natural immunity to avoid recurrent conditions [11]. As has been already stated, Ayurveda aims at overall balance of health through topical and ingested medicinal formulation. Ayurvedic formulations are devised on the premise that health and beauty are mutually dependent. In current times, lifestyle changes affect the health adversely. Some of the characteristic features of contemporary lifestyle are sedentary living,
erratic schedules, exposure to ambient pollutants and ingestion of harmful chemicals in food and medicines [12]. The lifestyle effects are seen in varied forms, most easily and widely observed in issues such as dandruff. Dandruff leads to loss of lustre and health of the hair, which in extreme cases may also lead to loss of hair.

In Ayurveda, dandruff correlates with Darunak, as mentioned in Kshudrarogadhikaar. Darunak is predominantly ascribed as Vatakaphaj and is a disease/disorder of the scalp. The symptomatic indications in Darunak (as in dandruff) are Kandu (Itching), Rukshata (Dryness), Keshbhumikathinya (Changed normal structure of scalp) and Twaksphutan (Scaling).

Broadly, Ayurveda aims to treat dandruff by restoring the balance in the body by building the immunity through ingested medicinal formulations. However, Ayurveda also suggests topical application of lepa, dhupan, varti, kaval, gandusha and basti.

*Bhaishajya Kalpana* is one of the facets in Ayurveda that lays down the guiding principles of dosage preparation based on availability, acceptability (subject-specific) and nature of ailment/complaint. The principle aim is to make use of natural abundance, adequate potency, ease of application, all time availability and cost effectiveness in the preparation of the medicines for all age groups [13]. *Lepa kalpana* commonly known as topical medicaments has been an established practice for external application on the skin or the mucosal membrane for treating local infections/disorders [14].

2. AIM AND OBJECTIVES OF STUDY

2.1 Aim

Pharmaceutical development, Standardization and Clinical Evaluation of Efficacy of Polyherbal Hair pack and Gel in management of Dandruff in comparison with standard market preparation containing tea tree oil.

2.2 Objectives

1. To establish the Standard Operating Procedure of Polyherbal Hair Pack and Hair Gel
2. To assess quality control parameters of Polyherbal Hair pack and Hair gel
3. To evaluate efficacy of Polyherbal Hair pack, hair gel and market sample of gel containing tea tree oil in the management of dandruff
4. To compare efficacy of hair pack, hair gel and standard market preparation containing tea tree oil

3. MATERIALS AND METHODS

Present work will be conducted under following headings.

3.1 Pharmaceutical Study

This study is related to drug preparation in which three different batches of Hair pack will be prepared to establish pharmaceutical standardization. Pharmaceutical study will be done in following steps;

- **Procurement of Raw materials:** All required raw materials will be procured from field and authentic reliable sources.
- **Authentication of Raw materials:** Raw drugs will be verified and authenticated by Department of Dravyaguna of MGAC & RC. Raw drug will be standardized as per A.P.I. Table 1 show contents of Hair pack and their quantity. Below is the flow diagram (Figure 1) of method of preparation of Hair pack.

| S. N. | Ingredients       | Part Used         | Quantity   |
|------|------------------|-------------------|------------|
| 1    | Amalki           | Fruit             | 1 part w/w |
| 2    | Yashtimadhu      | Root              | 1 part w/w |
| 3    | Bibhitaki        | Fruit             | 1 part w/w |
| 4    | Brahmi           | Panchang (Whole plant) | 1 part w/w |
| 5    | Nagarmotha       | Tuber             | 1 part w/w |
| 6    | Methibeej        | Seed              | 1 part w/w |
| 7    | Japapushpa       | Flower            | 1 part w/w |
| 8    | Haritaki         | Fruit             | 1 part w/w |

Table 1. Ingredients and quantity of hair pack
Flow diagram of unit procedure of preparation of Hair pack

3.2 Analytical Study

i. Description (Organoleptic characters)
- Sparsha (touch), Rupa (Appearance), Gandha (Odour)

ii. Physico-chemical parameters for Hair pack
- Loss on drying at 105°C, Total ash, Acid insoluble ash, Water soluble extractive, pH, HPTLC, GCP, Particle size, Microbial contamination, Pesticide residue will be seen.

Preparation of Hair Gel [15]

The above-mentioned drugs of hair pack will be made into Kwatha by following SOP [16]. Table 2 shows contents of Hair Gel and below is the flow diagram (Fig. 2) of method of preparation of hair gel.

Table 2. Ingredients and quantity of Hair Gel

| Sr.no. | Ingredient               | Proportion   |
|--------|--------------------------|--------------|
| 1      | Kwatha (Decoction)       | 1000 ml      |
| 2      | Sodium benzoate          | 0.8gm        |
| 3      | Carbopol aqua            | 8 gm         |
| 4      | Triethylamine            | As required  |

a. Preparation of Hair Gel

1-part coarse powder of hair pack

↓

4 parts water

↓

Boil till ½ remains

↓

Cool

↓

Add Sodium benzoate and Carbopol aqua

↓

Add Triethylamine

↓

Mix well. Leave for 24 hours till it sets into gel consistency. Store in air-tight container.

Fig. 2. Flow diagram of gel preparation
b. Analytical study of Hair Gel

- Organoleptic tests
  Sparsh (Touch), Roop (Colour, appearance), Gandha (Odour)
- Physico-chemical Parameters
  pH, Viscosity, Homogeneity, Spreadability Test, Skin Irritation Test, TLC, Microbiological Test.

3.3 Clinical study

Both dosage form hair pack and hair gel will be assessed in the patients of Darunak (Dandruff) of pubertal to middle age group (16 to 55 years).

**Study Design:** Randomized interventional parallel 3 arm study

**Study type:** Pharmaceutical, Analytical and Clinical study

**Study site:** Department of RSBK, MGACHRC, Salod, (H) Wardha

3.3.1 Participant’s Inclusion criteria

- Subjects visiting Mahatma Gandhi College of Ayurved hospital
- Volunteers willing to participate and giving informed consent
- Subjects of either sex, age group 16-55, suffering from Darunak (Dandruff) to be included randomly
- Subjects not applying any medicine on scalp skin 4-6 weeks prior to the study

3.3.2 Participant’s exclusion criteria

- Subjects having signs and symptoms of dandruff as inflammation, infection and any other skin disease.
- Diagnosed subjects of HIV (Human Immuno deficiency Virus)
- Subjects taking any kind of medicines oral as well as topical application on scalp
- Pregnant and lactating mothers.
- Conditions where head wash is contraindicated like pratishyay (rhinitis), ardit (facial palsy)
- Subjects suffering from chronic metabolic disorders and malignancies.

**Dose and route of application:** as per requirement depending on surface area of scalp and hair length, topical route.

**Drug Dose Decision:** Exact dose for topical application of Hair pack and Hair gel for Dandruff cannot be mentioned as it will depend on hair density and length of hair. It depends on the area of scalp which may vary from person to person.

Hair pack will be prepared by using powder and water in 1:1 ratio and soaked for an hour to get a homogenous mixture. Application of uniform layer of paste and gel on the scalp and hair is required.

3.4 Drug Application Duration

In Ayurvedic classical text the application of lepa formulation is recommended as per severity of disease. For treatment of Darunak (Dandruff) looking at current lifestyle and hectic schedule it will be recommended to apply once a week for 6 weeks. To compare effects of Hair pack and Hair Gel both the dosage forms will be applied for same duration.

3.5 Method of Application

Volunteers will be explained about application method of hair pack and gel.

Before application of Hair pack and Hair Gel volunteers will be asked to clean their hair with their regular washing procedure on the day prior to application of the pack or Gel.

Then they will be asked to apply Hair pack and Hair Gel on scalp to form a thin layer (in ancient texts the suggested thickness is ½ angul; it is equivalent to approximately 0.48 cm thickness evenly spread on the scalp and hair) and to keep for about an hour or till hair pack dries up to 70%-80% as lepa should be removed before it dries fully.

On partial drying removal of pack and washing instructions will be followed.

**Drug Application timing:** Morning time, before bath will be preferred.

**Study Schedule:** Table 3 denotes the study schedule to be conducted on volunteers.

3.6 Sample Size

To find out therapeutic potential of this innovated Hair pack and Gel the study will be conducted on 90 volunteers (30 in each group).
Table 3. Study schedule

| Number of Volunteers | Medicine | Duration                          | Time                  | Route Of Administration |
|----------------------|----------|-----------------------------------|-----------------------|-------------------------|
| 30 each (for the Hair Pack, Hair Gel and market gel) | Hair pack, Hair gel and market gel containing tea tree oil | Once a week for 6 weeks | Morning, 1 hour          | Topical                 |

3.7 Methodology

The volunteers will be informed about the study protocol. Willing participants will be randomly selected as per compartment generated table. Clinical research format will be prepared and validated. Prior to the study approval will be taken from IEC, MGACHRC, Salod (H) Wardha and CTRI registration will be done.

After selection, each participant will be tested individually by the scholar for following sign and symptoms [parameters]: Kandu (itching), Rookshata (dryness), Twaksputana (scaling), KeshaChyuti (hair fall). These Ayurvedic parameters will be assessed by gradation scale.

Trichoscopy test will be carried out to analyze scalp condition, flaky, sticky or any changes of scalp. Before and after treatment photographic evaluation will be done and presented.

After inclusion in study protocol each participant will receive the respective treatment from day one for 6 weeks. A container of 1kg hair pack, 500 gm Hair Gel and 1 container of market Hair Gel will be given to them. Instruction regarding application of pack and gel will be given to them. Telephonic reminder will be given weekly to remind them for application of hair pack and hair gel. In person follow up will be taken weekly on 8th, 15th, 22nd, 29th, 36th and 43rd day.

After completion of the treatment for 6 weeks on next day (44th day) each participant will be assessed with Ayurvedic and modern parameters.

Individuals, who will miss even 1 application of drug in total 42 days, will be dropped out from the clinical study. Post treatment follow up will be taken for next 6 weeks.

Each participant will be provided a bind leaflet (Diary) which includes time of application, dose of applied pack and gel, missing days if any, washing details (day and material), feel after application (soothing/irritation) and if any untoward effect observed. They will be instructed about how to fill that leaflet and asked to inform the doctor for adverse effect if any.

3.8 Assessment Criteria

The subjective Assessment Criteria as under [17].

Table 4. Assessment criteria (Kandu)

| Grade | Severity rating               |
|-------|-------------------------------|
| 0     | No Itching                    |
| 1     | Mild, tolerable (1 to 2 times a day) |
| 2     | Moderate, intolerable (3 to 4 times a day) |
| 3     | Severe, Intolerable (5 to 8 times a day) |

Table 5. Assessment criteria (Rookshata)

| Grade | Severity rating                       |
|-------|--------------------------------------|
| 0     | No Dryness                            |
| 1     | Mild, Dryness with rough skin         |
| 2     | Moderate, Dryness with scaling        |
| 3     | Severe, Dryness with cracking         |
Table 6. Assessment criteria (Twaksputana)

| Grade | Severity rating                        |
|-------|----------------------------------------|
| 0     | No scaling                             |
| 1     | Mild, scaling 1/4th part on vertex     |
| 2     | Moderate, scaling is more than ½ part  |
| 3     | Severe, complete scaling               |

Table 7. Assessment criteria (KeshyaChyuti)

| Grade | Severity rating                           |
|-------|------------------------------------------|
| 0     | 1 to 5 hair fall on combing/washing      |
| 1     | Mild, (less than 20 hair fall in combing/washing) |
| 2     | Moderate, (more than 20 hair fall in combing/washing) |
| 3     | Severe, (20 hair fall on simple hand strength) |

For assessment of effect of Hair pack & Gel and market Gel, before and after treatment scores of Ayurvedic parameters will be considered. Before and after photographic reports obtained from Tricoscopy will also be considered.

The Subjective criteria for the ailment will be graded as under:

Severe: 3; Moderate: 2; Mild: 1; Cured: 0. These gradations will be tabulated for:

1. Dry Scalp
2. Scaling
3. Pruritus
4. Erythema
5. Hair fall

Post-test assessment will be tabulated as under corresponding to the grades above, noted prior to treatment.

A. Full mitigation: 75 – 100% relief
B. Significant improvement: 50-74% relief
C. Mild improvement: 25 – 49% relief
D. Unsatisfactory: < 25% improvement from the pre-test condition

3.9 Observation and Results

- Observations will be noted and presented in the form of tables, chart, photographs etc.
- The data will be analysed with application of suitable inferential statistics

3.10 Method of Data Analysis

Statistical analysis will be done by applying suitable test. The tool used for the statistical tests will be SPSS. Hypothesis testing will be done using the corresponding tests at significance level of $p=.05$ so as to validate the statistical significance of the sample population. A comparative study of the effect of the hair pack and the Gel and its comparison with market gel will also be carried out to indicate the relevance of the proposed formulation and physical form.

4. DISCUSSION

Present research focuses on the tenets of Bhaishajya Kalpana to evaluate a new combination of topical formulation. The basic Ayurvedic principles of ease of availability (natural abundance), cost effectiveness, and ease of topical application keeping in consideration the demands of current lifestyle trends and client preferences will be followed to provide a holistic remedial solution to varied issues in hair healthcare such as dandruff, loss of lustre, weak strands, breakage, and loss of hair. The intended ingredients in the formulation
of the lepa are suggested keshya drugs Yashtimadhu [18], Japapushpa [19], Methibeej [20], Bramhi [21], Triphala [22], Nagarmotha [23] and Bhringraj [24-25]. This formulation has been devised in accordance with the overarching guiding principles of Ayurveda that encourage individual preference and ease of preparation and application [26,27]. The methodology of formulation and preparation will follow the procedures outlined in Yukti and Sanyog Sanskaar diligently. Considering current lifestyle and trending preference amongst users, a standardized formulation in both, pack and Gel form will be prepared. The Gel form is easier to carry and apply, and also has a better shelf life [25]. The efficacy of the drug will be tested by comparing the effect of conventional hair packs and the proposed Ayurvedic Gel formulation for its efficacy in dandruff. The dosage and frequency will be suggested at the outset and following clinical assessment, the researcher expects to establish the efficacy, acceptability and outcome of the proposed poly herbal Hair pack and Gel formulation (of dosage and frequency of application). Studies on efficacy of different Ayurvedic preparations were reported [28-30]. Few of the related studies were reviewed [31-33].

5. CONCLUSION

The present available treatment for dandruff does not provide complete remission of symptoms for long duration and it is very expensive. Thus the newly designed herbal formulation will provide significant result in controlling dandruff and its associated symptoms and modified dosage i.e. gel will overcome the limitation of powder and provide a cost effective cosmetic product in controlling dandruff.

6. STRENGTH OF STUDY

Herbal formulation safe and easy to use preparation will be formed.

7. LIMITATIONS OF STUDY

Hair pack efficacy is assessed by only one liquid media.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT AND ETHICAL APPROVAL

Informed written consent of each participant will be obtained prior to study. Prior to clinical study clearance from human ethics committee will be obtained. Prior to the study approval will be taken from IEC, MGACHRC, Salod (H) Wardha and CTRI registration will be done.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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