Evaluation of the Clinical Efficacy and Safety of “Anti-dandruff Hair Cream” in the Treatment of Dandruff

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INTRODUCTION:

Dandruff (also called scurf or Pityriasis capitis) is caused due to excessive shedding of dead skin cells from the scalp. It affects 5% of the population and mostly occurs after puberty, between 20 and 30 years. Dandruff affects males more than females. It is characterized by scaling of the scalp, and is frequently associated with seborrhea, which is the precursor of seborrhic dermatitis.

It is normal for skin cells to die and flake off, and is, in fact, quite common. Some people, however, either chronically or as a result of certain triggers, experience an unusually large amount of flaking, which can also be accompanied by redness and irritation. Dandruff is a common problem faced by people who are exposed to dust and other pollutants. Excessive scaling of the scalp tissue is also common in people who share combs and hair brushes. Dandruff may also be caused due to infection of Malassezia furfur fungus.

Excessive flaking can also be a symptom of seborrhic dermatitis, psoriasis, fungal infection, or excoriation associated with infestation of head lice. Dandruff is a global phenomenon and can cause social or self-esteem problems.

Current available treatment options for the management of dandruff include therapeutic use of zinc pyrithione, salicylic acid, imidazole derivatives, glycolic acid, steroids, sulphur, and tar derivatives. However, these agents have certain limitations, either due to poor clinical efficacy or due to compliance issues. Furthermore, these drugs are unable to prevent recurrence, which is the commonest problem.

Ayurveda, an Indian system of medicine, cited several plants that are useful against various causes of dandruff, without producing any side effects. Anti-dandruff Hair Cream, an herbal preparation, contains safe and effective natural ingredients for relieving symptoms of dandruff for those with normal hair. Using this cream helps remove flakes and eliminate the fungus, and hence, provides relief from dandruff. Regular use can also reduce recurrence of dandruff.

Anti-dandruff Hair Cream is a polyherbal formulation recommended for the treatment of dandruff and contains the extracts of Cicer arietinum, Rosmarinus officinalis, Ocinum sanctum, and oils of Melaleuca leucadendron, Pongamia glabra, Azadirachta indica, Sesamum indicum, and Vitis vinifera. This study was planned to evaluate the clinical efficacy and safety of “Anti-dandruff Hair Cream” in the management of dandruff.

Aim of the study:

This study was planned to evaluate the clinical efficacy and safety (short- and long-term) of “Anti-dandruff Hair Cream” (Batch No. FD/ADH/05) in the management of dandruff.

Study Design:

This study was a prospective, open, non-comparative, phase III clinical trial. The study protocol, case record forms, regulatory clearance documents, product related information, and informed consent forms were submitted to “The Institutional Ethics Committee” and were approved by the same.

MATERIALS AND METHODS

Inclusion criteria

A total of 50 patients, who were diagnosed as suffering from moderate to severe form of dandruff with dry/damaged hair, were included in the study.

Exclusion criteria

Patients with concomitant severe scalp infection, history of hypersensitivity to shampoos/cosmetics, children below 18 years of age, patients with preexisting severe systemic disease necessitating long-term medication, patients with genetic and endocrinial disorders, and those patients who refused to give informed written consent were excluded from the study. Pregnant and lactating women were also excluded from the study.

Study procedure:

A baseline history was obtained in order to determine the patient's eligibility for enrolment in the trial. The baseline assessment included personal data, a description of symptoms and details of past medical history (family history of dandruff and history of possible exacerbating factor/s). All the patients were advised to apply and massage the “Anti-dandruff Hair Cream” to the hair roots at bedtime, twice a week for a period of 6 weeks. All the patients were asked to adhere to “Anti-dandruff Hair Cream” only as a treatment for dandruff, and no other medicated topical application was allowed.

Follow-up and monitoring:

All the patients were followed-up for a period of 6 weeks and at each weekly follow-up visit, they were asked about the frequency of the
application. Clinical assessment of scalp lesions was done objectively (by doctor) and also subjectively (by patient). Thorough scalp examination was done after completion of 1 week and at the end of the study. The severity of the dandruff symptoms (itching, white scales, hair fall) was recorded on a score scale from 0 to 3 (0=Nil, 1=Mild, 2=Moderate, 3=Severe).

Patients, with the help of linear analogue scale, did the subjective assessment, and the extremes of linear analogue scale were predefined as “no improvement” and “total cure” from dandruff.

**Primary and secondary endpoints:**

The predefined primary efficacy endpoints were reduction in dandruff lesions, reduction in overall scalp inflammation, split hair, and healing of existing scalp lesions. The predefined secondary safety endpoint measures were incidence of adverse events and overall patient compliance to the treatment.

**Adverse Events:**

All the adverse events, either reported by the patients or observed by investigators were recorded in case record forms, with the information about severity, date of onset, duration and action taken regarding the study drug. The relation of adverse events to the study product was predefined as “Unrelated”, “Probable”, and “Possible”.

Patients were allowed to voluntarily withdraw from the study if they experienced serious discomfort during the study or sustained clinical events requiring specific treatment.

**RESULTS:**

All the 50 patients (38 female, 12 male) completed the study. The mean age of patients was 29.5 years.

There was highly significant reduction in the mean score of dandruff in all patients at the end of the study. Also there was significant reduction in the mean scores of itching, white scales, and hair fall at the end of the study (Table 1).

38 out of 44 (86.36%) patients who had severe dandruff, after treatment got excellent improvement, 4 (9.09%) got good improvement while 2 (4.54%) got moderate improvement. 36 out of 42 patients had severe hair fall, out of whom 32 (88.88%) got good improvement, while 4 (11.11%) got excellent improvement. 38 patients out of 44 had severe itching, out of whom 36 (94.73%) got good improvement, while 2 (5.26%) got moderate improvement (Table 2).

In subjective evaluation, 46 out of 50 patients (92%) experienced remarkable overall improvement. The overall likeability for Anti-dandruff Hair Cream was excellent in 46 out of 50 patients (92%), good in 2 patients (4%), and moderate in 2 patients (4%). The overall nourishing effect of the Anti-dandruff Hair Cream observed by patients at the end of the study was excellent in 43 out of 50 patients (86%), good in 6 patients (12%), and moderate in 1 patient (2%) (Table 3).

There were no clinically significant adverse reactions, either reported or observed, during the entire study period and overall compliance to the treatment was excellent.

**DISCUSSION:**

A person’s entire body surface continuously sheds dead skin cells and the skin itself sheds every 24 days. Dandruff, the shedding of dead skin cells from the scalp at an excessive rate, is the result of the normal growing process of scalp skin cells.

Dandruff may be caused by several different factors, but the exact underlying cause of dandruff is unknown. Dandruff, the visible desquamation of scalp, is the mildest manifestation of seborrhic dermatitis. Dandruff usually is a result of *Pityrosporum ovale* infection combined with multiple host factors. The severity of dandruff varies from mild to exfoliative erythroderma. Seborrhic eczema is a more severe form of dandruff, which affects the skin around the eyebrows, nose, ears, face and forehead, and the typical scales are yellowish and greasy with inflamed skin.

The aim of dandruff treatment is to reduce the number of *Pityrosporum ovale* on the scalp, and the goals of therapy are to reduce morbidity and prevent complications.

**Table 1: Response to Anti-dandruff Hair Cream**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>No. of patients</th>
<th>Pre-treatment</th>
<th>Post-treatment</th>
<th>% of response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dandruff</td>
<td>50</td>
<td>6*</td>
<td></td>
<td>88%</td>
</tr>
<tr>
<td>Itching</td>
<td>44</td>
<td>2*</td>
<td></td>
<td>95%</td>
</tr>
<tr>
<td>Hair fall</td>
<td>42</td>
<td>3*</td>
<td></td>
<td>93%</td>
</tr>
<tr>
<td>White scales</td>
<td>35</td>
<td>2*</td>
<td></td>
<td>94%</td>
</tr>
</tbody>
</table>

*p<0.05 as compared to pre-treatment

**Table 2: Improvement in patients after treatment**

<table>
<thead>
<tr>
<th>Result</th>
<th>Patients with</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dandruff</td>
</tr>
<tr>
<td>Excellent</td>
<td>86.36%</td>
</tr>
<tr>
<td>Good</td>
<td>9.09%</td>
</tr>
<tr>
<td>Moderate</td>
<td>4.54%</td>
</tr>
</tbody>
</table>

**Table 3: Overall subjective evaluation of Anti-dandruff Hair Cream**

<table>
<thead>
<tr>
<th>Result</th>
<th>Likeability</th>
<th>Nourishing effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>92%</td>
<td>86%</td>
</tr>
<tr>
<td>Good</td>
<td>4%</td>
<td>12%</td>
</tr>
<tr>
<td>Moderate</td>
<td>4%</td>
<td>2%</td>
</tr>
</tbody>
</table>
Dandruff is a natural process, which cannot be eliminated and can only be managed and controlled.

This study observed a significant reduction in mean scores of itching, white scales, hair fall, and dandruff. Subjective evaluation revealed remarkable improvement.

The excellent anti-dandruff action of “Anti-dandruff Hair Cream” might have been due to synergistic antifungal, anti-inflammatory, and local immunostimulatory actions of its ingredients.

The essential oils of Maleleuca leucaadendron possess anti-microbial and anti-fungal activities. It has been proved to have anti-fungal activity against infections of the skin and mucous membranes caused by different sensitive organisms as well as in the treatment of dandruff, a mild form of seborrhoeic dermatitis. Significant improvement was observed in the total area of involvement score, the total severity score, and the itchiness and greasiness components of the patients’ self-assessments. It also has anti-histaminic effect.

The principle ingredients of Rosmarinus officinalis are caffeic acid, phenolic diterpenes (carnosic acid, carnosol and 12-O-methylcarnosic acid), caffeyl derivatives (rosmarinic acid), and flavones (isosculetellarein 7-O-glucoside and genkwanin). The extract of Rosmarinus officinalis has been shown to have potent antioxidant activity, in both aqueous and lipid systems.

The principle ingredients of Vetiveria zizanioides are valencene, 9 octadeccamidene, 2, 6, 10, 15, 19, 23-hexamethyl-2, 6, 10, 14, 18, 22-tetracosahexene, 1, 2 benzendicarboxylic acid, dioxyctylester, and terpenoids (monoterpenes, sequiterpenes and triterpenes).

The principle constituents of Vitis vinifera are flavonoids (gallic acid, catechin, epicatechin, resveratrol, gallocatechin, gallic acid, and ellagic acid) and glycosylated stilbenes: (Z)-piceatannol-(3, 5, 3’-4’-tetrahydroxystilbene)-3-O-beta-d-glucopyranoside and (E)- and (Z) resveratrol-(3, 5, 4’-trihydroxystilbene)-4’-O-beta-d-glucopyranoside, which have potent antioxidant potential.

Figure 1: Effect of Anti-dandruff Hair Cream on clinical parameters

![Graph showing effect of anti-dandruff hair cream on clinical parameters](image)

The principle ingredients of Ocimum sanctum are fatty acids (stearic, palmitic, oleic, linoleic and linolenic acids), cirsilanol, cirsimartian, isothymusin, isothymonin, apigenin, rosmarinic acid, and eugenol. Ocimum sanctum has significant anti-inflammatory activity against prostaglandin E2, leukotriene, and arachidonic acid. Ocimum sanctum acts as antimicrobial agent.

Cicer arietinum, contains 2-(2-methoxy-4,5-methylenedioxophenyl)-6-hydroxybenzofuran, which is an antifungal phytoalexin previously isolated from the roots of chickpea, Cicer ssp. and shows antimicrobial activity.

Sesamum indicum is found to be rich in linolenic acid, sesamol (475 mg/100 g), a potent natural antioxidant, and alpha-tocopherol (32 mg/100 g), the most active form of vitamin E. It is possible that the beneficial effects seen with Anti-dandruff Hair Cream may be a sum total effect of these ingredients.

This study also indicates safety of Anti-dandruff Hair Cream and it does not have any adverse effect on the eye structure.

CONCLUSION

This study observed significant symptomatic and clinical improvement in dandruff in 6 weeks. The excellent antidiandruff action of “Anti-dandruff Hair Cream” might have been due to the synergistic antifungal, anti-inflammatory and local immunostimulatory actions of its ingredients. It is also well tolerated by the patients. Therefore, it may be concluded that “Anti-dandruff Hair Cream” is effective and safe in the management of dandruff.

REFERENCES