

**A controlled evaluation of Herbal Speciality**

# **"SCALPTONE"**

**in prevention of Excessive Hair Loss.**

**by**

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## **ABSTRACT**

1. A double blind placebo controlled clinical trial was conducted to assess the effectiveness of a herbal speciality "Scalptone" in the treatment of excessive hair loss and associated symptoms.
2. A total of 50 patients were included in the trial. Half the number of patients received "Scalptone" and the other half "Placebo."
3. The recovery rate from excessive loss of hair was 76% in the group which received "Scalptone". The results were highly significant ( $p < 0.001$ ).
4. There was marked improvement in associated symptoms in Scalptone group e.g. itching, irritation and dryness of scalp. Thinning and splitting of hair and smarting of hair roots.'
5. Both dandruff and greasy skin was totally cured in the Scalptone group.

## **INTRODUCTION**

Few clinical trials have been performed to evaluate herbal therapy (1,2). This situation is largely due to the rationale of herbal prescription by which the precise nature of the treatment is adapted to the specific symptoms of a patients suffering from a given disease. The treatment is based on the simillimum principle, using infinitesimal concentrations of drugs which have the ability to induce, in healthy individuals, symptoms similar to those presented by sick persons. Although a regular feature of herbal treatment is that two patients who have the same disease are liable not to benefit from the same treatment, a school of thought soon developed (3) that certain diseases could be treated with drug mixtures tailored to the disease characteristics alone.

Herbal physicians are far from reaching agreement about such drugs which would be prescribed without taking account of the particular symptoms of each patient nevertheless these drugs are gaining popularity among large sections of the medical profession and among the public who buy them over-the-counter.

These preparations provide the opportunity to design conventional trials in a way that

has not so far been possible with regular unitarian drugs.

The following experiment deals with a drugs of the former category. Its action on the treatment of excessive hair loss was evaluated. It is a homoeopathic preparation currently in the market.

## **METHOD**

Patients included in the study were chosen from those who attended O.P.D. at Lok Kalyan Samiti Hospital, New Delhi and who agreed to participate in the experiment after a formal briefing. The treatment allocation of active drug (Scalptone) or Placebo was made on a randomised double-blind basis. The standard treatment dispensed was 4 Tablets of "Scalptone" 4 times daily for 26 weeks. The Placebo whose presentation was identical was made of lactose and administered in the same dosage for same duration. The doses were dispensed with a code number which was identified only after analysis of the data. The patients were examined on the day of reporting and thereafter at an interval of one, two, four, eight, twelve and sixteen weeks. To be eligible to take part in the clinical trials, the patients had to be 21 years old and over, to suffer from excessive hair-loss and at least two of the following symptoms: Itching or irritation or else dryness of scalp, thinning or splitting of hair, dandruff, smarting of hair roots and greasy skin. The active drug is commercialised under the trade mark "Scalptone" by SBL Ltd. Its composition is as follows :

### **Each Tablets contains :**

Acidum fluoricum	..	30
Acidum phosphoricum	..	30
Natrum muriaticum	..	30
Arsenicum album	..	30
Calcarea phosphorica	..	30
Badiaga	..	30

Excipients q.s. to one tablet of 100 mg.

## **ACTION OF INDIVIDUAL COMPONENTS**

**Acidum Fluoricum** : Alopecia. Falling out of hair, complaints of old age, or the prematurely aged, with weak, distended blood vessel.

**Acidum Phosphoricum** : Hair grey early in life, falls out. Hair thins out. Exposure to the ravages of acute disease, excess grief and loss of vital fluids. Mental debility first; later physical.

**Natrum Muriaticum** : Affects hair follicles. Alopecia. Greasy Skin. Seborrhoea. Falling out of hair. Sensitiveness of scalp.

**Arsenicum Album** : Scalp itches intolerably; circular patches of bare spots; nightly burning and itching, dandruff. Scalp very sensitive; cannot brush hair.

**Calcarea phosphorica** : Head hot, with smarting of roots of hair. Itching on the scalp, provoking scratching.

**Badiaga** : Dandruff; scalp sore, dry, tetter-like. Hair dry, itching of the scalp.

## **RESULTS**

A total of 50 patients were included in the trials. Table - 1 shows that the two groups : Active drug (Scalptone) and Placebo were reasonably similar. The most common symptoms at inclusion in the trials were excessive loss of hair, itching of scalp, irritation of scalp, dryness of scalp, thinning of hair, splitting of hair, smarting of hair roots, dandruff and greasy skin. The patients were examined on the day of reporting and subsequently at an interval of 1, 2, 4, 8, 12 and 16 weeks. It was noted that the recovery rate from excessive loss of hair within 16 weeks of treatment was 76% in the group which received "Scalptone" and 0% in the Placebo group (Table - 2). The associated symptoms were markedly eliminated in the group receiving Scalptone as compared to Placebo group. Itching of scalp was eliminated in 90% of the patients, irritation of scalp in 94%, dryness of scalp in 91 %, thinning of hair in 85%, splitting of hair in 90% and smarting of hair roots in 95%. Both dandruff and greasy skin was totally cured (100% each) in the Scalptone group. Compared to this, there was no significant improvement of these symptoms in Placebo group (Table - 3).

**TABLE - 1  
INITIAL COMPARISON BETWEEN TREATMENT GROUPS**

	<b>Active Drug (Scalptone)</b>	<b>Placebo</b>
Number eligible case	25	25
Sex - ratio M/F	11/14 (0.78)	12/13(0.92)
Age* (years)	45.7 (1.7)	43.7 (1.9)
* mean (mean deviate)		

**TABLE - 2  
RECOVERY RATE FROM FALLING OUT OF HAIR WITHIN  
16 WEEKS OF TREATMENT**

	<b>Active Drug (Scalptone)</b>	<b>Placebo</b>
Recovered n	n=25 19	n=25 0
%	76	0

P< 0.001 Highly significant

**TABLE - 3**  
**SIGNS & SYMPTOMS PROFILE IN**  
**"SCALPTONE" & PLACEBO GROUPS**

Symptoms & Signs	Active drug (Scalptone) group							Placebo						
	OD	1W	2W	4W	8W	12W	16W	OD	1W	2W	4W	8W	12W	16W
Excessive loss of hair	25	24	23	20	16	13	6	25	25	25	25	25	25	25
Itching of scalp	21	20	16	13	9	5	2	22	22	21	21	21	21	21
Irritation of scalp	18	18	15	11	5	3	1	18	17	17	17	17	17	17
Dryness of scalp	24	20	17	13	8	3	2	24	23	23	23	22	22	22
Thinning of hair	21	19	15	12	9	5	3	22	22	21	21	21	21	21
Splitting of hair	20	16	14	11	8	4	2	20	20	19	19	19	19	18
Smarting of hair roots	24	17	13	6	4	2	1	23	23	23	22	22	22	22
Dandruff	23	15	11	5	3	0	0	21	21	21	20	20	20	20
Greasy Skin	21	19	9	4	2	0	0	20	20	20	19	19	19	19

## **DISCUSSION**

The scalp is the name for the layer of skin and its underlying tissues which cover the top of the human skull. Stretching from the back of the neck to just above the eyebrows, the scalp contains the skin in which the hairs of the head are embedded and grow. Like other parts of the body, the scalp is prone to a variety of diseases and disorders, including familiar problems such as excessive hair loss and dandruff. The scalp needs sensible treatment if it is to stay healthy and provide an ideal environment for the hair-producing tissues that are found there in profusion.

The skin of the scalp contains hair-producing cells capable of giving rise to thick hair in profusion up to 50cm (20 in) or more long. The hair themselves are dead and are largely made by living cells clustered at the base of blind-ended tubes called hair follicles. Each hair is lubricated by oil secreted from a sebaceous gland at the side of the hair follicle. Also associated with each hair is a muscle, whose contractions can make the hair stand up, and a nerve ending which is what makes a tug of the hair painful. Immediately beneath the taut skin of the outermost layer of the scalp is a layer of tissue containing an extensive network of blood vessels.

Of all the problems that afflict the human scalp, the one that undoubtedly causes most concern is excessive hair loss or baldness. The latter can result from illness, or it may come about through an accident of genetics. Excessive hair loss may be a symptom of some other problem and is often of the patchy variety called alopecia areata. It may result from a nervous tugging at the hair, from mental shock, as the result of disorders in the output of hormones by the pituitary and thyroid glands or come about through scalp infections such as ringworm or more general body infections like typhoid fever. In all these cases, the hair either grows back of its own accord; or regrows to its normal extent when the underlying cause of the problem is corrected.

The other, more common type of excessive hair loss which afflicts less than 5% of women but more than 40% of all men is the hereditary type. In both men and women, there is a natural cycle of scalp hair loss and regrowth, in which, on average, some 100 hairs a day are shed. What happens in hereditary excessive hair loss (or balding) is that the mechanism of hair regrowth does not work properly and instead of being replaced by thick, strong hairs, the lost hairs are substituted by soft, downy villus hair, similar to the ones that grow on a baby's scalp and body.

While excessive, hair loss (or baldness) may be either mild or so severe that virtually all the normal hair is lost, studies of baldness have shown that it takes on certain patterns. The baldness may start, for example at the crown and spread outwards, forward and backward, or begin at the temples so that the hairline gradually recedes. And it may begin as early as the twenties or as late in life as the sixties or seventies. The exact pattern of hair loss, and its age of onset, is related to the genetic nature of the balding effect, since the age that balding starts, and the pattern it takes, certainly run in families.

It is thought that although men and women may both carry a baldness gene, in men the gene is expressed or shown up but in women it is not, unless it is present in a double dose. The reason for this is that the expression of the gene depends on the secretion of male sex hormones which interact with the genetic message and cause baldness.

25 patients suffering from Excessive hair loss who received herbal speciality "Scalptone" showed a recovery rate of 76%. On the other hand the recovery rate was nil in equal number of patients suffering from excessive hair loss who received Placebo. The positive effect of the herbal speciality cannot be explained in our present state of knowledge and thus calls for further investigations.

The evidence that Scalptone treats and maintains a healthy scalp is provided by studying itching, irritation and dryness of scalp. Itching of scalp reduced from 21 to 2 in patients receiving Scalptone whereas it reduced from 22 to 21 only in patients receiving Placebo tablets. Similarly, irritation of scalp declined from 18 to one in patients receiving Scalptone whereas it declined from 18 to 17 only in patients receiving Placebo. Again dryness of scalp which was present in 24 patients in each group decreased to two patients in Scalptone group and 22 in Placebo group respectively.

Thinning and splitting of hair and smarting of hair roots provided an additional evidence of healthy scalp. Thinning of hair declined from 21 to 3 patients in Scalptone group whereas it decreased from 22 to 21 patients in Placebo group. Splitting of hair which was 20 in each group decreased to two in Scalptone group and 18 in Placebo group respectively.

Dandruff is an excessive scaling of the dead skin of the scalp. It forms part of a seborrhoric tendency; an overproduction of sebum, the natural oil secreted by glands in the skin. It affects all the areas where hair grows, especially the scalp. In the great majority of cases of dandruff, there is no known cause, but there are indications that heredity, diet or an upset in the body's hormonal balance may be contributory factors. In severe case there may be excessive greasiness of the skin and hair, patches of scalp redden and tiny openings appears which ooze and form hard yellow crusts. Serious complication occur if any cracks in the affected skin open and crusted areas become infected, leading to the development of impetigo, a contagious skin infection. Occasionally the condition can turn into eczema; the redness and inflammation worsen and the skin discharges a clear fluid. In our present study of 23 patients suffering from dandruff who received active drug "Scalptone", the recovery rate was 100%. On the other hand in 21 patients suffering from dandruff who received "Placebo", only one patient recovered. Even greasy skin which was present in 21 patients of Scalptone group, was completely cured in all the patients.

While pharmacological studies have been published recently (4,5,6) conventional clinical trials published in the non-herbal literature are exceptional (2). Reviews (1,7) stress the weakness of most herbal trials and underline the methodological difficulties of such an enterprise. This tends to enhance the suspicion of those who are detractors of this therapeutic approach. Although it may be enjoying a revival among sections of the population at large and among part of the medical profession, only rigorous clinical experiments will allow vindication of this approach.

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### **REFERENCES**

1. Aulas, J.J. (1985) La revue Prescruie, 5, 34-37
2. Reilly et al. (1986) Lancet II, 881-886
3. Finella.F. (1877) Ed. Bailliere, Paris.
4. Cazine et al (1987) Human. Tox. 6, 315-320
5. Davenas et al (1988) Nature. 333, 816-818
6. Davenas et al(1987) Eur. J. Pharmac. 165,313-319
7. Scofield, A.M. (1984) Br. Hom. J. 73, 161-180 & 211-226

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