

## CLINICAL TRIAL OF CERTAIN AYURVEDIC MEDICINES INDICATED IN VITILIGO

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**ABSTRACT :** An Ayurvedic preparation consisting of dried ginger, black pepper, pippali and leadwort root fermented in cow's urine was given internally and a paste made of several medicinal herbs including *Psoralea corylifolia* for external application was tried in patients with vitiligo. 4 out of 10 patients had relief within six months of treatment. Three patients had relief with adverse reaction on the skin and other did not respond. The preparations did not have any adverse effect in the body as seen from haematological parameters and biochemical tests.

### **Introduction**

Vitiligo is an acquired disfiguring pigmentary anomaly of the skin manifested by depigmented white patches surrounded by a normal or hyper-pigmented border. The most commonly affected areas are face, upper part of the chest, dorsal aspects of hand, axilla, groins, eyes, mouth, ears, nipples, genital organs, anus, elbows and knees (1). It affects all races but more predominant in tropics. Pathogenesis of vitiligo has been ascribed to auto-immunity, heredity, neurohumors and trauma (2).

Although spontaneous re-pigmentation occurs in 25% of the patients, vitiligo is seldom satisfactorily treated. The major available drug is trimethyl psoralen (3). Use of hormones such as ACTH has also been

recommended (4). In the present paper two Ayurvedic preparations have been clinically tested on 10 patients with vitiligo.

### **Materials and Methods**

**Patients:-** All patients undergoing the treatment had an onset of the disease between 6 months to two years. Age of the patients varied from 17-60. Both male and females were admitted. General health condition of the patients was satisfactory and the following biochemical and haematological parameters were measured before, during and after the treatment and using standard techniques (5): (a) body weight (b) white blood cell (WBC) count (c) differential count (d) haemoglobin (e) blood sugar (f) serum bilirubin (g) serum urea (h) SGPT (i) serum alkaline phosphatase.

Statistical analysis of the data was carried out using student's 't' test. Photographs of the affected areas were taken.

**Preparation of medicine for internal administration:** All the crude drugs were purchased from local market and were identified. Dried ginger (*Zingiber officinale*)-250 gms; Black pepper (*Piper nigrum*) 250 gms, Pippali (*Piper longum*) 250 gm and Leadwort root (*Plumbago zeylanica*) 250 gms were crushed and added to 20 liters of Cow's urine and fermented in a sealed container for 15 days. After fermentation it was filtered and stored in tightly closed bottles. 30 ml of this extract was mixed with 60 ml of boiled water and given twice daily before food.

**Preparation of the paste for external application:** *Physalis peruviana* (whole plant) 100 gms; *Calotropis gigantea* (leaf) 100 gms; *Cassia fistula* (leaf) 100 gms, *Euphorbia antiquorum* (stem) 100 gms, *Psoralea corylifolia* (seed) 400 gms were powdered and boiled in cow's urine (2 liters) and red sulphide of mercury (100 gms) was added to form a fine paste. The paste was dried to a powder. This powder was wetted with water and applied externally on the patches in the morning and exposed to sunlight for 15 minutes.

Application of the paste was avoided in areas of mucous membrane.

Both the drugs were continued for six months before their effects were finally evaluated. Patients who had positive response continued using the drug and others were advised to change the therapy.

## Results

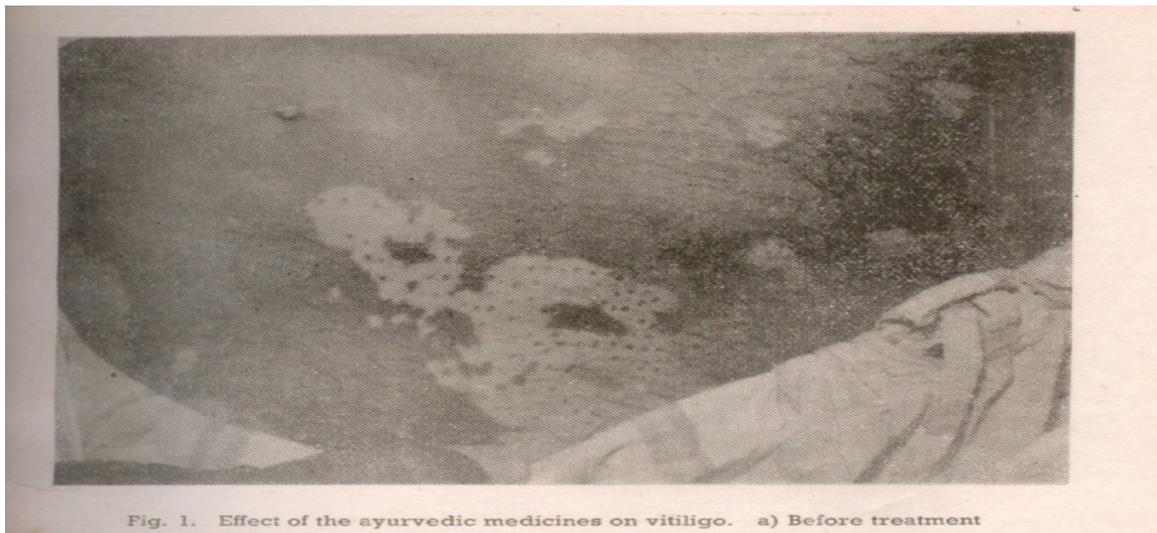
All patients treated during the course of this study had vitiligo spread over different parts of the body. Administration of the paste was discouraged on mucous membranes such as inside the lips and genitals. The drug given internally had a pungent odour but was well-tolerated by all patients. The paste produced a burning sensation after exposure to sunlight and was not tolerated by some patients. Adverse reaction including blisters, itching and swelling could be seen on the areas where the paste was applied but disappeared after its use was discontinued.

Table I shows the result of the administration of the drug in the patients. As seen in the table, 6 out of 10 patients had positive response to the treatment evidenced by increased melanin formation. However two of these had skin reactions. The other four did not respond and one patient had severe skin reactions. Photographic evidence of the success of the treatment is given in Fig.1.

TABLE 1

SUMMARY OF THE EFFECT OF ADMINISTRATION OF DURGS TO VITILIGO PATIENTS

Sl. No	Age & Sex	Sites	Response of treatment
1.	40,M	Whole body	Responded
2.	18,F	Lip	Responded, discontinued
3.	60,M	Leg, Lip	No respond, reaction
4.	16,M	Leg, Penis	Leg responded
5.	47,F	Lip, Leg	Not responded
6.	21,M	Neck	Responded
7.	17,F	Leg	Responds with reaction
8.	31,M	Hand, Leg	Responds with reaction
9.	25,M	Palms	No response
10.	34,M	Penis	No response



The patients who responded to the therapy had vitiligo patches mainly on leg, back of the neck, chest and thigh whereas in unresponsive cases the patches were on the lips, genitals and palms which are usually more difficult to heal due to decreased melanosomes in this area.

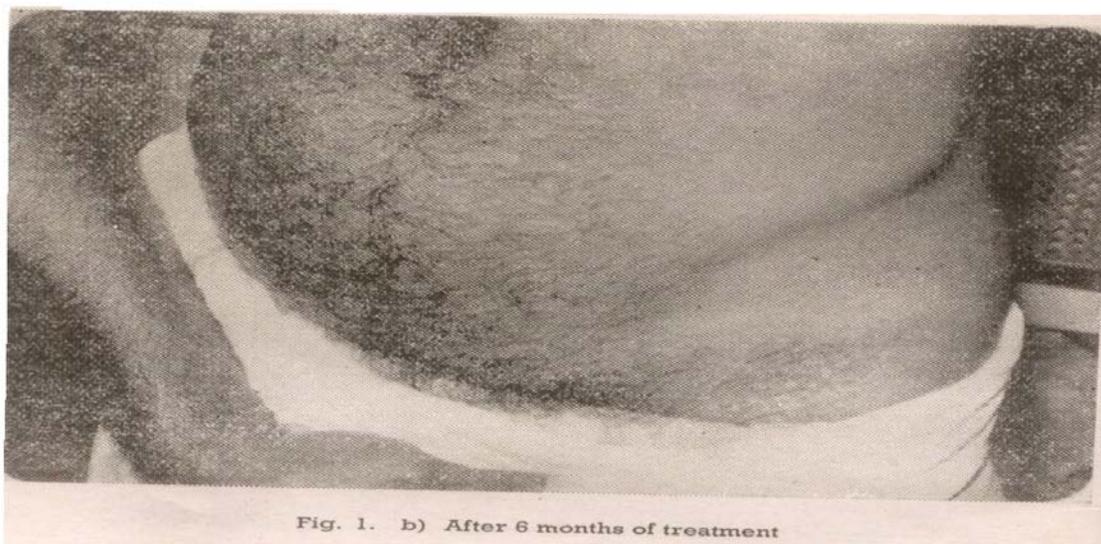
The haematological parameters of this patients undergoing treatment is given in Table II. The average hemoglobin in these patients did not change after 6 months of treatment. The total W.B.C showed a slight increase ( $P < 0.05$ ) suggesting that the drug may cause immune-stimulation. The differential count did not change very much. However it was found that the percentage of eosinophils increased to 30% in the case of two patients who had adverse reaction towards the drug indicating allergic manifestation.

The biochemical parameters of the patients before and after treatment are shown in Table III. The most interesting finding is the significant reduction in blood sugar ( $P < 0.001$ ). There was also a slight increase in serum bilirubin and serum urea ( $P < 0.01$ ) indicating an increased hepatic function. However the marker enzymes of hepatic injury such as alkaline phosphatase and SGPT did not increase.

The administration of the drug did not have any appreciable change in blood pressure and body weight in any of the patients.

### Discussion

The efficacy of the preparations evaluated by the present study has been known among the practitioners of ayurveda, but a systematic study to evaluate the claim was not carried out earlier. The present report is therefore the first of its kind.



In the present report an internal drug and a paste for external application were prescribed to 10 patients with vitiligo and it was found that six of them had sustained positive response. The allergic manifestation of the paste was the major problem with the drug and was especially seen in patients who were sensitive to sunlight. It was found that the drug caused more reliable

and sustained response in patients who did not have any reaction towards the drug. The internal drug was found to produce no remarkable change both in the haematological parameters and biochemical tests. Interestingly, eosinophils (30%) were increased in patients who experienced.

**TABLE 2**

**Haematological parameters of vitiligo patients before and after therapy**

	Values before treatment	Values after treatment	Significance
Haemoglobin	12.49 ±1.12	12.37±0.85	P<0.1
Total W.B.C	8310 ± 864.6	9600±1358.9	P<0.05
Poly morphoneutrophils	60.3±12.3	6.03±14.96	P<0.1
Eosinophils	7.6±4.7	9.4±13.9	P<0.1
Lymphocytes	32.8 ± 9.75	29.2±11.2	P<p.1

Values are average o ten patients

**TABLE 3**

**Biochemical parameters of Vitiligo patients before and after therapy**

Parameters	Values before treatment	Values after treatment	Significance
Blood sugar	114.6 ± 26.7	72.4±12.49	P<0.0001
Blood urea	17.2±5.92	23.3±6.97	P<0.05
Bilirubin	0.55±0.085	0.68±0.10	P<0.01
SGPT	11±8.4	10.2±5.71	P<0.1
Alkaline phosphatase	3.01±1.5	5.1±2.96	P<0.1

Values are average of ten patients

reaction. But even in these patients both biochemical and haematological parameters were similar.

The blood glucose in the patients showed a significant decrease ( $P < 0.001$ ). This may be mainly because of hypoglycemic effect due to the presence of anabolic steroids in the urine(6). However this needs further experimentation.

The mechanism of the drug is not known at present. The administration of the drug produced a significant increase in WBC count and slight increase in serum urea and bilirubin, indicating an increased immunostimulation and hepatic function. As the marker enzymes for hepatic toxicity has not been significantly increase it could be interpreted that the drug does not produce any hepatotoxicity. It is known that some of the ingredients of the internal medication such as Piper longum stimulate the hepatic function (7) and hence may stimulate the synthesis of melanin precursors. Moreover the paste has drugs with known free radical-producing systems like psoralin which may produce photo reaction with the melanin precursors present on the skin.

Thus the effect of the formations may be due to increased immunostimulation, hepatic function and photo reaction.

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