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Clinical Study to Evaluate the Efficacy and Safety of Vitimelin Tablet and Vitimelin Oil in Vitiligo with Special Reference to Shwitra

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Abstract

Introduction: Vitiligo is one of the skin diseases that causes cosmetic problems. Childhood vitiligo differs from adult vitiligo in many ways. Even if the treatment of the disease is the main goal for a dermatologist, a better understanding of vitiligo may be helpful for better management of the patient.

Aim: To evaluate the efficacy and safety of *Vitimelin* tablets and *Vitimelin* oil in patients with Vitiligo/*Shwitra*.

Material and methods: Thirty clinically diagnosed *Shwitra* (vitiligo) patients were chosen for the proposed clinical study. All patients have been given one *Vitimelin* tablet three times a day and *Vitimelin* oil for local application. After 10 minutes of application, a sunlight/UVA lamp was exposed to the affected area for 20 minutes.

Result: After 3 months of treatment, the number of black spots increased by 28.13%, the colour of the patches was obtained with 29.82% relief, and the size of the observed patches decreased by 29.03%.

Discussion: It can be concluded that the trial treatment stimulates the formation of melanin pigment at the level of the skin and melanocytic cells. The formation of blackish spots also indicates the deposition of melanin pigment generated by melanocyte cells during skin production, which has been regulated by melanocyte-secreting hormones of the pituitary and pineal glands. These results indicate that the hormonal impacts of the trial drug may contribute to the correction of pathology.

Keywords: *Shwitra*, vitiligo, vitimelin tablet, *Shwitra*

Introduction

Vitiligo is a pigmentary disorder that is acquired, long-lasting, and marked by the loss of cutaneous melanocytes and problems with how they normally work. This causes areas of skin to lose their pigmentation and become amelanotic over time. The cause is unknown, but it could be due to genetics, autoimmunity, neurological factors, toxic metabolites, or a lack of melanocyte growth factors.

In general, vitiligo in children is different from vitiligo in adults. Even if the treatment of the disease is the main goal for dermatologists, a better understanding of vitiligo may be helpful for better management of the patient. Modern science says that *Shwitra* is the same as leucoderma or vitiligo. Vitiligo is a broad term for a group of skin diseases that make the skin lose its color.

Vitiligo can affect different amounts of skin in different places and in different ways for different people. It can also get in your hair, eyes, and mouth. A person's mental health and social life are also affected by Vitiligo/*Shwitra* because the skin patches make them look poor and cause problems with their appearance. When a child has vitiligo, it can cause them and their parents to go through a lot of emotional pain,

which can lower their quality of life. All of these factors could lead to a person with this disease being shunned by their peers.

In Ayurveda, all skin diseases are placed under the name "*Kushtha*," which is further broken down into "*Maha Kushtha*" and "*Kshudra Kushtha*." But in Brihatrayi, *Shwitra* has not been added to the list of different kinds of *Kushtha*. Various *Acharyas* later grouped this under various forms of *Kushtha*. Even though *Shwitra* is listed with other types of *Kushtha*, it is not the same as *Kushtha* because it is not contagious and only affects *Twaka*. It is also different because *Nidana*, *Asadhya Lakshana*, and chronicity are also different. Due to the deterioration of *Dhatus* like *Rasa*, *Rakta*, *Mamsa Meda*, and *Tridoshas*, the prognosis for the disease gets worse. This depends on how long the disease has been going on and which *Dhatus* are involved. Since then, it has also been considered under the *Rakta Pradoshaja Vikara*.

In Ayurveda, *Pitta* has five various forms. The *Bhrajak Pitta*, which is on the skin, is in response to a person's beauty and skin color, as well as how their personality has been shown. Skin problems can occur when the normal functioning of *Bhrajak Pitta* is interrupted by external or internal factors.

Consequently, because of this, *Shwitra* has been defined as "*Pittavikrati Janyavikara*," a condition associated with *Bhrajak Pitta's* abnormal functioning.

Shwitra can be related to vitiligo because one of the symptoms is an uneven distribution of melanocyte pigment, which is also a sign of vitiligo. Vitiligo is a common inflammatory disorder that affects 0.4-2% of the world's population. About half of the people who have it are children. In 25% of cases, the onset occurs before the age of 10 years. The disease may manifest at any age, but it is most prevalent in children under 10 years of age or in the 2nd decade of life. Vitiligo may be the main symptom of certain hereditary and congenital causes. Although these hereditary disorders are not curable, the disfigurement or discoloration of the skin leading to social stigma is the main concern of the patient, resulting in social, psychosocial, and cosmetic apprehension. Hence, the present study aims to provide relief on the above facets so that a person can lead a happy, "socially accepted" life, although the root cause of the disease can't be corrected.

The goal of this study is to find an effective, simple, and low-cost way to treat *Shwitra/vitiligo* based on *Ayurveda* principles. This is because *Shwitra* affects a large number of people, especially children, and the number of cases is rising every day.

Aims and Objectives

To evaluate the efficacy and safety of tablet Vitimelin and oil Vitimelin in patients with Vitiligo/*Shwitra*" was planned.

Material and Method

Study Type: Open-label clinical trial.

Source of Data: A total of 30 patients were selected for the proposed clinical study. Patients were selected from the OPD and IPD *Kaumarabhritya* department, National Institute of Ayurveda, Jaipur.

Dose

- **Vitimelin Tablet-1 tablet TID (500 mg each)**
[*Vitimelin* tablet contains 3 herbs *Bakuchi*, *Bhumi-Amalaki*, and *Jatamansi*]
- **Local Application-Vitimelin Oil:** (Two times on patches/affected area, after 10 min. of application sunlight/UVA lamp exposed on the affected area for 20 min.)
[The *Vitimelin* oil contains 5 herbs: *Bakuchi Tail*, *Tila Tail*, *Gandhnakuli*, *Chitrak*, and *Karanj*]
- **Duration:** Total duration of the study was 3 months.
- **Follow up:** Follow-up was done every 15 days during the intervention period.

Inclusion Criteria

- Children of either gender of the age group between 10-16 years.
- Children having classical signs and symptoms and diagnosed as Vitiligo/*Shwitra*.
- The patient should be capable of obeying the instruction related to the course of therapy.

Exclusion Criteria

- Patches more than 30% of the body, Broad continuous irregular patches.
- Children with albinism were excluded.
- White anesthetic spots are characterized by leprosy.

- Patches in the genital area and only the lip area are excluded from the study.
- The patient suffering from any other known systemic and chronic disease/autoimmune disorder.

Assessment Criteria

- i). Alterations in the colour of the Vitiligo patches and black dots appearing were recorded periodically with photography.
- ii). The number of dots was counted, and the joining of two or more dots (blackish), if any, was noted and recorded in subsequent follow-ups with grading.
- iii). Changes in the size of the observed patch, if any, were also recorded.
- iv). Scoring was between 0-9.
- v). Vitiligo area scoring index (VASI) [Score 0-100]

$$\text{VASI} = \sum [\text{Surface (Hand unit)}] \times [\text{Residual Depigmentation}]$$

Objective criteria

- The objective parameter was assessed before and after the finding of laboratory parameters i.e., CBC, ESR, Liver function test, Renal function test.

Results

- **The Number of Black Spots in Observed Patches:** The number of black spots increased by 28.13%, respectively, which is a statistically very significant (P value 0.00091) result.
- **Color Changes in Observed Patches:** After statistical analysis, a very significant result (P value 0.00017) was obtained with 29.82% relief. Within a few days of receiving the trial medicine, the whitish patches turned pink, followed by the emergence of blackish dots.
- **Size of Observed Patches:** The size of the observed patches decreased by 29.03%, respectively, which is a statistically highly significant (P value 0.00157) result. This implies that clinical efficacy decreased with rapidly appearing blackish spots and colour changes, which may be due to prior conditioning of the body by the trial drug.
- **Impact on VASI Score:** The VASI score was observed as follows: before treatment, it was 2.60; and it was found to decrease to 1.73 after treatment, with a mean difference of 0.87, showing relief of 33.61% with a highly significant (P-value 0.000000694). The statistically highly significant result was with trial medicine. The mean haemoglobin count before treatment was 12.7 g/dl, and it was found to have raised to 13.58 g/dl after treatment with a mean difference of 0.88, showing relief of 6.9% with a statistically highly significant result (P value 0.00157).
- **Neutrophil, Lymphocyte, Monocyte, Eosinophil, and ESR:** Had no significant result; it means the trial drug has not been involved in the inflammatory and allergic reactions. Hence, we can say that drugs have no adverse effects.

There were no significant changes observed in the Liver function test (TSB, total protein, S. albumin, S. globulin, SGOT, SGPT) found, so we can say that there is no adverse effect of the trial drug on liver functions.

There were no significant changes in the kidney function test (serum urea, creatinine serum), so we can say that there is no adverse effect of the trial drug on kidney functions.

Discussion

Table 1: Vitimelin Tablet

| Content | Rasa | Guna | Virya | Vipaka | Dosha Karmukta | Properties | |
|-------------------------------------|------------------------------|---------------|--------------|---------------|---------------------------------|--|--|
| | | | | | | Ayurveda classics | Contemporary science |
| <i>Bakuchi</i> ^[1] | <i>Katu, Tikta</i> | <i>Ruksha</i> | <i>Shita</i> | <i>Katu</i> | <i>Kaphara, Vatahara</i> | <i>Kusthghn Jantughma, Vrana Ropana</i> ^[2] | Antioxidants, Anti-inflammatory, Antibacterial ^[3] |
| <i>Bhumi-amalaki</i> ^[4] | <i>Tikta, Kashaya Madhur</i> | <i>Laghu</i> | <i>Shita</i> | <i>Madhur</i> | <i>Raktapitta, Kapha Shamak</i> | <i>Kusth-vishapaha</i> | Hepatoprotective, Anti-oxidant, Anti-viral ^[5] |
| <i>Jatamansi</i> ^[6] | <i>Tikta, Kashaya</i> | <i>Laghu</i> | <i>Shita</i> | <i>Katu</i> | <i>Tridosha Shamaka</i> | <i>Medhya, Varnya, Kushthaghna Nidrajanana</i> | HepatoprotectiveNeuroprotective Anti-convulsant ^[7] . |

Bakuchi

Bakuchi is also known as “*Shwitraghni*”^[8]. It is used in inflammatory diseases, mucomembranous disorders, dermatitis, and edematous conditions of the skin^[9]. Due to *Tikta, Katurasas; Ruksha, Ushnagunas; Kusthaghna*, and *Rasayana* properties, it eradicates *Shwittra, kushtha*, and *krimis* and secretes healthy *Pitta*^[10].

Bhumi-Amalaki

Bhumi-amalaki has wide use in *Yakrit Vikara*, it helps in the stimulation of the liver and improves liver function. *Yakrita* is the site of origin of *Raktavahasrotasa*^[11]. *Bhumi-amalaki* acts on the formation site of the *Rakta Dhatu* & breaks the basic pathogenesis of *Kushtha*. It acts as a blood purifier. *Sheeta Guna* and *Tikta, Kashaya*, and *Madhur Rasa* of the *Bhumi-amalaki* help to balance *Pitta* and induce healing of the lesion with blackish discoloration, indicating melanin deposition.

This suggests that an increase in the *Pitta Dosha* locally stimulated the *Bhrajaka Pitta* to cause an increase in the *Varna* of the skin.

Jatamansi

In Ayurvedic texts, *Jatamansi* is considered *Kantiprada/Varnya*, which means regulating the skin's normal color. It has several *Karmas* like *Tridosha Shamaka* (balances all three *Doshas*), *Pittaghni/Raktadosha Shamaka* (expels out *pitta* and *Rakta dosha*), and *Medhya* (beneficial to the brain). *Jatamansi* has Antidepressant activity^[12], which helps the person who has to suffer from this disease may undergo the situation of feeling distressed, stigmatized by their condition, and social boycott. It has also Hepatoprotective, Neuroprotective, Hypotensive, Hypolipidemic, and Anti-convulsant activities^[13].

Table 2: Vitimelin Oil

| Content | Rasa | Guna | Virya | Vipaka | Dosha-Karma | Properties | |
|---------------------------------|----------------------------------|-----------------------------|--------------|---------------|--|---|---|
| | | | | | | Ayurveda classics | Contemporary science |
| <i>Bakuchi</i> ^[14] | <i>Katu, Tikta</i> | <i>Ruksha</i> | <i>Shita</i> | <i>Katu</i> | <i>Kaphara, Vatahara</i> | <i>Kusthghn Jantughma, Vrana Ropana</i> ^[15] | Antioxidants, Anti-inflammatory, Antibacterial ^[16] |
| <i>Til-tail</i> ^[17] | <i>Madhur Katu Tikta Kashaya</i> | <i>Guru, Snigdha, Ushna</i> | <i>Ushna</i> | <i>Madhur</i> | <i>Vataghna, Kapha-pitta Vardhan</i> | <i>Twachya, Keshya, Vranehitah</i> | Anti-inflammatory, Anticancer ^[18] |
| Sneh-Pakdravya | | | | | | | |
| <i>Chitrak</i> ^[19] | <i>Katu, Tikta</i> | <i>Tikshna</i> | <i>Ushna</i> | <i>Katu</i> | <i>Shlesma-Vatahar</i> ^[20] | <i>Shwitraghna</i> ^[21] <i>Kusthghn</i> ^[22] | Hepato-protective, Anti-microbial, Anti-inflammatory, Anticancer, |
| <i>Karanj</i> ^[23] | <i>Katu, Tikta,</i> | <i>Tikshna</i> | <i>Ushna</i> | <i>Katu</i> | <i>Kapha-vataghna</i> | <i>Krimjit Kusthajit</i> ^[24] | Anti-ulcer, Anti-oxidant, Anti-Inflammatory ^[25] . |
| <i>Gandh-nakuli</i> | <i>Katu, Tikta, Kashaya</i> | <i>Laghu, Ruksha</i> | <i>Ushna</i> | <i>Katu</i> | <i>Kapha-vataghna</i> | <i>Kusthaghna, Vishnasini, Krimighn</i> ^[26] | Anti-Inflammatory, Antipruritic ^[27] |

Bakuchi Oil

The *Rasas* of *Bakuchi* are *Katu, Tikta*, and *Katu Vipaka Ruksha Guna*. *Sroto-Dushti* is removed by the *Katu-Tikta Rasa, Ruksha Guna*. *Bakuchi's Katu Vipaka* also improves local blood circulation, supplying nutrition to the cells and helping in the proper production of *Bhrajak Pitta* in the skin. *Bakuchi* has strong antioxidant properties. *Bavacin* and *Psoralidin* have an inhibitory effect on the granulation that is caused by the antigen^[28].

Chitrak

The heating effect of *Chitrak* boosts the circulatory process, thus removing skin ailments. This may have been caused by

the correction of *Bhrajaka pitta*. The anti-inflammatory and antibacterial properties of *Chitrak* provide calming and soothing effects for skin problems. The vitiation of *Kapha* and *Vata* is the main *Doshic* involvement in *Shwittra*. Due to *Kaphavatahar* properties, *Chitrak* pacifies *Kapha* and *Vata*, thus controlling disease from its root cause^[29].

Karanj

Karanj is used extensively for the treatment of skin diseases (*Kushtha*) due to its *Kushthaghna* property. It has *Katu, Tikta Rasa, Tikshna Guna*, and *Ushna Veerya*. It helps in the removal of *Ama* and local *Sanga* from the *Kapha Dosha*. The Removal of *Sanga* helps in proper *Dhatu Poshana*, resulting

in the *Dhatu Vridhi*. There, metabolism will be corrected by stimulating the melanocyte-stimulating axis, which will initiate melanin production.

Gandhanakuli

Mast Cell Stabilizing and Antipruritic activity of *Aristolochia Indica* [30]: Ethanol extract of *Aristolochia Indica* showed significant protection against mast cell degranulation induced by sheep serum and also showed Antipruritic effect in terms of reduced scratching response. According to Jessy Elizabeth Mathew *et al.*, It will relieve itching by working on the Pruritic response induced by *Bakuchi*.

Following the application of vitimelin oil, all participants in this study were exposed to sunlight. These effects have a direct impact on melanin pigmentation by stimulating the skin's underlayer lipid layer. Ayurveda's treatment of *Shwitra Roga* is based on the Agni. Pitta is a manifestation of Agni that's found inside the body. *Brajaka Pitta*, which is found in the skin, also doesn't have enough in *Shwitra*. According to *Samanya Vishesh Siddhanata*, the intake of *Samana Guna*, *Karma*, and *Dravyas* can increase *Agni*, or *Pitta* in the body. The sun, which represents the *Tejo Mahabhuta*, thus helps the body's *Agni* when exposed to it. For repigmentation, studies have shown that UVA and NBUVB (narrow band UVB) stimulate melanocytes. Depending on the intensity of UV light exposure, light overexposure with the full UV spectrum can result in marked pigmentation and diffuse skin darkening [31].

Conclusion

The Trial medicine contains various herbs in it which have anti-inflammatory, anti-bacterial, and anti-microbial activities. The maximum medicine that is used has *Katu*, and *Tikta* Properties, which are *Kusthghna*. In *Ayurveda* main cause of *Kustha Rogas* is *Ama* so the maximum drugs which are used in medicine are *Deepak-Pachak* which digests the *Ama* and breaks the *Samprapati*. Some drugs also act as *Rasayan* which act on all *Rasadisapta Dhatus*. By working on the *Dhatu* level, it's again working on *Samprativighatan* as *Dhatus* are *Dushya* and *Dosha-dushyasamurchna* take place here. According to modern science, vitiligo is an autoimmune disease. There are many studies already done on the drugs that are used in trial medicine, i.e., *P. corylifolia (Bakuchi)* seed extract has been reported to stimulate the immune system in mice. Administration of the seed extract was also found to inhibit antibody-forming cells and stimulate natural killer cell activity and antibody-dependent cellular cytotoxicity [32].

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