A clinical evaluation of Bakuchi Hartal Lepa and Amalaki Khadir Kashayam in the management of Switra (Vitiligo) - A Pilot Study

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ABSTRACT

Vitiligo is usually patchy depigmentary disorder, due to reduced or absent melanocytes. Most paediatric cases present after first decade of life with well-demarcated milky-white or hypopigmented patches. In Ayurveda vitiligo is known as Shwitra and described under Kushtha. The Tridoshas (Vata, Pitta, and Kapha) and Dhatus (such as Rasa, Rakta, Mamsa, and Meda) vitiations are what give rise to this variety of Kushtha in the classical Ayurvedic texts. The disease is significant primarily because it raises cosmetic concerns, which ultimately cause the sufferer to experience several socialised psychological stigmas. Ayurveda provide effective and safe treatment protocol for vitiligo. In the present Pilot study Amalaki-Khadir Kashaya with Bakuchi (Prakshep Dravya) is used as internal medication and Bakuchi, Hartala Lepa with Gomutra as external therapy in 8 patients. The Gunas of these drugs are opposite to Doshas responsible for Switra. This study shows significant decrease in number of hypopigmented patch as well as improvement in the psychological status of the patient.

Key words: Vitiligo, Switra, Kushtha Roga, Amalaki-Khadir Kashaya, Bakuchi

INTRODUCTION

In Ayurveda the disease Sweta Kushtha or Switra is grouped under skin diseases and mentioned in Kushtha Roga Chikitsa Adhyaya¹ characterised by whitish discoloured patches on the body. Vitiligo occurs when pigment producing cells die or stop functioning. It can affect any part of the body including mouth, hair & eyes. It can begin at any age.²

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The prevalence of vitiligo ranges from 0.5% to 1%.² Its highest incidence has been reported amongst Indians from the Indian subcontinent. India is considered to have the highest prevalence in the world, at about 8.8%.²

The family history has been found to affect the prevalence of Vitiligo amongst such people prevalence is high ranging from 7.7% to more than 50%. The mean age of onset is also earlier in those with a positive family.³

The gender-wise distribution of the disease is equal affecting adults and children of both sexes are equally. However, more females were reported to have this condition. It may due to the higher social impact posed by this condition on women and girls. Nearly 50% of the patients Vitiligo developed before the age of 20 years and in almost 70-80% patients before the age of 30.³

Most of the vitiligo cases reported beginning of disease during the period of active growth. Vitiligo is a multifactorial polygenic disorder with a complex pathogenesis. It is related to both genetic and
nongenetic factors. Although several theories have been proposed about the pathogenesis of vitiligo, the precise cause remains unknown. Generally agreed upon principles are an absence of functional melanocytes in vitiligo skin and a loss of histochemically recognized melanocytes, owing to their destruction. However, the destruction is most likely a slow process resulting in a progressive decrease of melanocytes. Theories regarding destruction of melanocytes include autoimmune mechanisms, cytotoxic mechanisms, intrinsic melanocyte defects, oxidant-antioxidant mechanisms, and neural mechanisms.

Medications and light-based therapies are available to help restore skin colour or even out skin tone, though result vary and are unpredictable and some treatment have serious side effects.

The disease is caused by various erroneous dietary habits & life style which ultimately aggravate the Tridoshas especially Kapha Dosha along with Rasa, Rakta, Mansa and Meda Dhatu. Many Ayurvedic formulations are used for the regeneration of melanocytes in the hypopigmented patches among which Bakuchi, Hartal, Khadir are some effective drugs mentioned in Ayurvedic texts. The present study was planned to study the efficacy of such drugs. 8 cases of Switra treating with Bakuchi Haratal Lepa and Amalaki Khadir Kashaya (orally) were analysed. On the basis of observation and result it was found that the Ayurvedic formulations were very much effective in managing the disease Switra.

Aim and Objective

To evaluate the effect of Bakuchi Hartal Lepa and Amalaki Khadir Kashayam in the management of Switra (Vitiligo)

Materials and Methods

Source of data

The patients suffering from Switra (Vitiligo) attending the OPD of Pt. Khushilal Shrma Govt. Ayurvedic Hospital Bhopal were screened and allocated to the study. Overall, 10 patients were included in the study fulfilling the diagnostic, inclusion and exclusion criteria.

A detailed history taking and physical examination were carried out in these patients. The clinical data along with the elaborated assessment of the condition were recorded in specially designed case proforma.

Among 10 patients, 8 completed the treatment. 2 patients did not complete the whole treatment due to unknown cause.

Study Design

The present study is a pilot clinical study conducted in the department of Panchakarma of Pt. Khushilal Sharma Govt. Ayurvedic College and Institute Bhopal.

Intervention Period: 21 days

Inclusion Criteria

▪ Patients suffering from Switra (Vitiligo).
▪ Duration of the disease being 1 to 2 years.
▪ Age between 16 and 60 years.
▪ Patients who are willing to participate in the study.

Exclusion Criteria

▪ Hypopigmentation due to scar formation as a result of burns or other injuries (Vranaja Switra).
▪ Patients with any chronic disease that needs regular medication.

Assessment Criteria

Patients were observed for 21 days. Assessment was done before the medical interventions. Then, patients were assessed on the 7th day and 14th day. Final assessment was done after completion of the therapy that is on the 21st day. Assessment was done based on the size, colour and number of the lesions. VETI score was used for assessment. [4]

VETI score:

(Percentage of head involvement × grade of tensity) +
(Percentage of trunk involvement × grade of tensity) ×
(Percentage of upper limbs involvement × grade of tensity) ×
(Percentage of lower limbs involvement ×
grade of tensity) 4+ (Percentage of genitalia involvement × grade of tensity) 0.1
The coefficients reported in this formula are based on percent of skin surface by the rule of nines. Accordingly, the coefficient of head is 1 (9:9=1), trunk and lower limb is 4 (36:9=4), upper limb is 2 (18:9=2) and genitalia is almost 0.1(1:9= 0.1).
- Percentage of involvement: p
- Tensity: T

\[ \text{VETI:} \ (Ph \times Th) + (Pt \times Tt)4 + (Pu \times Tu)2 + (Pl \times Tl)4 + (Pg \times Tg)0.1 \]
5 + 20 + 10 + 20 + 0.5 = 55.5
The maximum score of VETI is 55.5.

Statistical Analysis
After completion of the treatment results were statistically analyzed in the terms of mean score, standard deviation (SD), standard error (SE), paired t test, and p value at various levels.

Criteria for Overall Assessment
The total effect of the therapy on 8 patients of Switra was calculated by taking the mean of percentage of improvement. The final overall effect was graded as cured, marked improvement, moderate improvement, mild improvement, and no improvement [Table 1].

Table 1: Criteria for overall assessment of the intervention

<table>
<thead>
<tr>
<th>Percentage of improvement</th>
<th>Effect of Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 25%</td>
<td>No improvement</td>
</tr>
<tr>
<td>25% - 49%</td>
<td>Mild improvement</td>
</tr>
<tr>
<td>50% - 74%</td>
<td>Moderate improvement</td>
</tr>
<tr>
<td>75% - 99%</td>
<td>Marked improvement</td>
</tr>
<tr>
<td>100%</td>
<td>Cured</td>
</tr>
</tbody>
</table>

Treatment Regimen
Oral Medicine
Kashayam: Khadira Yavakut (heartwood powder) 1 part, Amalaki Phala Yavakut (Fruit powder) 1 part.
Prakshepa Dravya: Bakuchi Beeja Churna
Dose: 40 ml twice a day empty stomach [Table 3]

External application
Lepa: The paste is to be prepared with Shuddha Hartala Churna 1 part and Bakuchi Beeja Churna in 3 part, mixing with Gomutra (cow’s urine) [Table 2].

Process of Application: Patients were advised to apply Lepa over the hypopigmented/ depigmented patches in the morning and advised to expose to the sun between 8 AM and 10 AM for 20 to 30 min.

Table 2: Ingredients of Lepa

<table>
<thead>
<tr>
<th>SN</th>
<th>Name of Drugs</th>
<th>Botanical Name/ Chemical Name</th>
<th>Used part of the plant</th>
<th>Used form</th>
<th>Part</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Shodhit Hartal</td>
<td>Arsenic Trisulfide</td>
<td>-</td>
<td>Churna</td>
<td>1 Part</td>
</tr>
<tr>
<td>2.</td>
<td>Bakuchi</td>
<td>Psoralia corylifolia Linn</td>
<td>Beeja (seed)</td>
<td>Churna</td>
<td>3 Part</td>
</tr>
<tr>
<td>3.</td>
<td>Gomutra</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 3: Ingredients of Kashaya

<table>
<thead>
<tr>
<th>SN</th>
<th>Name of Drug</th>
<th>Botanical Name</th>
<th>Used Part of the Plant</th>
<th>Used form</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Khadira</td>
<td>Acacia catechu (Linn.f.) Willd</td>
<td>Sara (heartwood)</td>
<td>Churna</td>
<td>5gm</td>
</tr>
<tr>
<td>2.</td>
<td>Amla</td>
<td>Phyllanthus emblica</td>
<td>Phalamajja (Fruit)</td>
<td>Churna</td>
<td>5gm</td>
</tr>
<tr>
<td>3.</td>
<td>Bakuchi</td>
<td>Psoralia corylifolia Linn</td>
<td>Beeja (seed)</td>
<td>Churna</td>
<td>3gm</td>
</tr>
</tbody>
</table>

RESULT
The assessment was made by adopting the standard scoring methods related to vitiligo, which include the size and number of hypopigmented/ depigmented patches. (VETI Score)
1. Effect of treatment on the size of patches: Reduction of size of the patches was found to be significant at the end of treatment [Table 4 and Figure 1].

Table 4: Effect of treatment on the size of patches

<table>
<thead>
<tr>
<th>Criteria of assessment</th>
<th>Mean MD SD SE</th>
<th>Paired t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size of patches</td>
<td>BT 17.5      AT 5.1</td>
<td>4.2 0 5.2 6 1.8 6</td>
<td>6.6</td>
</tr>
</tbody>
</table>

2. Effect of treatment on the number of patches: The numbers of patches were significantly reduced after treatment [Table 5 and Figure 2].

Table 5: Effect of treatment on the number of patches

<table>
<thead>
<tr>
<th>Criteria of assessment</th>
<th>Mean MD SD SE</th>
<th>Paired t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patches</td>
<td>BT 7.2 AT 2.1</td>
<td>1.1 5 3.4 7 1.2 3</td>
<td>4.17</td>
</tr>
</tbody>
</table>

3. Effect of treatment on the basis of Vitiligo Extent Tensity Index (VETI) Score: The combined assessment of the extensiveness and pigmentation status was analysed both before and after the treatment by using the VETI Score. Significant improvement was observed in the patients in term of this criterion. [Table 6]

Table 6: Effect of treatment on the Basis of VETI Score

<table>
<thead>
<tr>
<th>Criteria of assessment</th>
<th>Mean MD SD SE</th>
<th>Paired t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>VETI Score</td>
<td>BT 12.1 AT 4.8</td>
<td>3.6 2.8 4 1.0 0</td>
<td>7.3</td>
</tr>
</tbody>
</table>

4. Mild improvement 01 12.5%
5. No improvement 00 00%

Considering the overall effect of the intervention, 50% of the patients had marked improvement, 12.5% of the patients were noted to have moderate and mild improvement and no patients were found with unimproved condition. [Table 7] Thus, the overall outcome of this study was significant, indicating that the trial drugs as per reference of the Ayurveda text have an effective role in the treatment of Switra.

**DISCUSSION**

Vitiligo is a skin disease characterized by milky white patches with hypopigmented border due to failure of melanin formation. This is a Tridoshaja Vyadhi with a predominance of Pitta, where Dushyas are Rakta (Blood), Mansa (Muscle), and Medadhatu (Fat Tissues). Since the response rate to the currently known treatments is so low, an effective treatment has yet to be discovered. Modern medicines are associated with so many complications and having various side effects with toxicity. Ancient Ayurvedic herbs, which are primarily used to address the disease’s aetiology, can be used to treat vitiligo.

In this study Amalaki, Khadir, Bakuchi and Hartal are main drugs.

Acharya Charaka has described Khadir as the best drug of choice for Kushta having Shamak effect on Rakta Dhatu and Pitta Dosha.

Ashtanga Sangraha explains this drug as best for the treatment of all kind of skin disease including Switra.

Laghu Guna, Tikta Rasa, Katu Vipaka and Sheeta Veerya of drug balance Kapha and Pitta Dosha.

Amalaki is rich in vitamin C and has antioxidant properties. It helps to boost the immune system and improves the production of melanin.

Bakuchi is a renowned herb that has been used in Ayurveda for centuries to treat skin conditions. It has been extensively used in hypopigmentation with great success. It contains psoralens, which on exposure to the sun rays brings out melanin in the depigmented lesions. Psoralea corylifolia is a proven antibacterial,
antistaphylococcal, antifungal, anti-inflammatory, vasodilator, skin photosensitizing, antitumour, immunomodulatory agent. It also contains bakuchiol, bavchinin, bavchin and corilin which have antioxidant properties, and has been found to stimulate melanin production in the skin. Melanin is the pigment with which the skin gets its colour. Vagbhata says that healthy Strotas are pillars of life and the abnormal state of Strotas is disease. Diets, life style that aggravate Dosha and lodge in the Dhatu are bound to disturb the functioning Strotamsi. Katu, Tikta Ras, Katu Vipaka, Ushna Virya and Ruksha Guna of Bakuchi correct Strotoduhi in Shwitra.

Purified Hartal, an arsenic compound, was used as a topical medicine in the study. Hartala was used in the Yoga along with Bakuchi. Haratala is best owed with immune modulating properties, and widely used for some autoimmune disorders in which the etiopathogenesis is deranged immunity.[10] Arsenic is absorbed through skin in addition to other routes. In Shwitra, the deranged immune system destroys the pigment synthesizing melanocytes. Haratala probably breaks this pathogenesis and prevents the self-destruction of melanocytes.[11] The Vyavayi and Ashukari properties of Hartala may help the drug to reach the site quickly and remove the obstruction of Srotas.[12] Gomutra is indicated in many skin conditions. It is having properties like Ruksha, Tikshna, Ushna, Laghu and having Krimihar, Ksharatva and Vata-Kaphashamaka effect. These properties induce inflammation when applied over skin with Bakuchi and Haratala. Lepa was applied in early morning because heat of the body comes out through the skin pores at night normally which is obstructed if applied at night.[13]

Probable mode of action of Lepa - Lepa has dominancy of Tikta-Katu Rasa with Katu Vipaka, Ushna Veerya, and Sara-Tikshna Guna. It also possesses Kushthaghna, Krimighna, Deepana, Pachana & Kandughana properties.[14] In Switra Lepa might have helped in Samprapti Vighatana. Bakuchi, Haratala and Gomutra (cow’s urine) are specially indicated for Shwitra.[15]

Local application of medicines causes inflammation at the site due to presence of Psoralen and Ushna property of Gomutra. It increases the blood supply hence more Rasa and Rakta Dhatu flow which brings back the normal skin colour.

CONCLUSION

A clinical trial with Bakuchi Haratal Lepa with Gomutra as external application and Amalaki Khadir Kashyam orally has shown encouraging results in the repigmentation of the affected skin. Not much complication was observed in the patients at the end of the study. So, this treatment protocol can be a good option for the management of Switra (Vitiligo). In the current study, as the sample is very small and the follow-up period is short, to arrive at a conclusion about the effectiveness and safety of the treatment, a clinical trial with a big sample size and a long follow-up period will be needed.

<table>
<thead>
<tr>
<th>Before treatment</th>
<th>After treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Before image" /></td>
<td><img src="image2.png" alt="After image" /></td>
</tr>
<tr>
<td><img src="image3.png" alt="Before image" /></td>
<td><img src="image4.png" alt="After image" /></td>
</tr>
</tbody>
</table>
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14. Bhavaprakash Nighthantu

15. Rasa Targasini 14-71

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