CLINICAL EVALUATION OF KAKODUMBARADI GHANAVATI (INTERNAL) AND AYORAJADILEPA (EXTERNAL) IN THE MANAGEMENT OF SWITRA (VITILIGO)
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ABSTRACT

OBJECTIVE:
To evaluate the efficacy of Kakodumbaradi Ghanavati (internal) and Ayorajadilepa (external) in the management of Switra. Switra (Vitiligo) is a hypopigmentation dermatological disorder involving mind and body, where in patient feels emotionally deranged and it effects the appearance and outlook of the individual there by person immersed in deep agony, in short it induces social stigma. METHOD: The trial drug Kakodumbaradi Ghanavati internal and Ayorajadilepa external are considered for the evaluation in Switra. The clinical study was undertaken on 30 patients in a single group. The hypothesis on the action of Kakodumbaradi Ghanavati (internal) has Kushtagna (curing skin diseases), krimighna (antihelmintic), varnya (promote complexion), Switraghna prabhava along with deepana (digestive), pachana (digestion), Bruhana (nourishing), Balya (strengthening) and Vrushya (aphrodisiac) properties and Ayorajadilepa is verified its external action to introduce potentially melanin pigmentation in this observational study. To assess the effect of treatment, color, number of mandalas (circular patches), VASI Score, hyper-pigmentation of margin, were considered. RESULTS: The results of the study are based upon the assessment of the subjective and objective criteria considered in the study. Mainly the objective parameters are considered to show the evidences of the relief in the study. The result encourages the Ayurvedic fraternity even though the cure is only 6.67% (2 patients) in the time bound study. Study reveals well responded listed as 26.66% (8) patients along with the 37.66% of moderately responded patients. In the study many causes made hindrances of the melanin repigmentation and 8 i.e. 26.66% patients fall under poor response. Only one patient i.e. 3.34% noticed as the no response patient in the entire study.

CONCLUSION: Subjective parameters viz. Rookshata (dryness), Parushata (roughness), Daha (burning), Kandu (itching), Guruta (heaviness) are not significant in the study but all objective parameters are highly significant as per statistical evaluation.

KEY WORDS: Ayorajadilepa, hypopigmentation, Kakodumbaradi Ghanavati, shwitra, vitiligo, VASI Score

INTRODUCTION
Switra is a dermatological disorder having its references cited in the Vedas (science). The term is combination of Swith and Rik. Swith means whiteness and Rik is suffix of ‘Shweta’ Dhatu. Shabdalakpadruma defined the term for white colored object. The Nirukti of the term reveals white color or changes toward white color. ‘Switra’ is a disease pertaining to Twak (skin) which turns the normal colour of the skin to white. The cardinal symptoms of Switra are the appearance of ‘Apa-
risravi shweta varna mandalas, on the skin that is depigmented patches or macles. These patches are more common in sun-exposed areas including the hands, feet, arms, face and lips. The change in appearance caused by this condition can affect a person’s emotional and psychological well being. Switra inflates an inferiority complex in the persons affected. Switra emerges as a sequel to irregular dietary habits, life style changes, and genetic predisposition.

Worldwide prevalence of Vitiligo is observed as 1% of the world population. This condition affects about 1-2% of the world’s population and 3-4% in India. All the races and both sexes are equally affected. Based on the clinical features of Switra, it can be correlated to vitiligo of the modern medicine. Vitiligo on the face is ranked 17th by WHO in world’s most disabling diseases. It is defined as a common acquired discoloration of the skin characterized by well circumscribed ivory or chalky white macles which are flush on to the surface. The hair over the patch may be white or normal. Vitiligo is a localized type of hypopigmentation disorder where single or multiple patches of hypopigmented area are seen. Either it might be symmetrical or nonsymmetrical.

Of the various treatment approaches offered by conventional medicine, from the good old PUVA therapy, to using corticosteroids, to epidermal grafts or cell culture techniques none is completely effective in all presentation of Vitiligo. Further some of conventional approaches have unacceptable side effects or either unaffordable or not easily accessible in all parts of the country. Ayurvedic treatment in this concern through holistic approach, can improves the patient’s appearance and restore the normal pigmentation of the skin. Since Vitiligo affects irrespective of poor and rich and as well as children and adults, a clinical study was planned to access the efficacy of an indigenous preparations based on the Ayurvedic principles. Thus the ‘Kakodumbaradi Ghanavati and Ayorajadilepa’ mentioned in Sahasrayoga and Yogaratnakara are selected for internal and external application respectively, as the contents of these drugs are easily available, economic and good result oriented. So the present study “Evaluation of the efficacy of ‘Kakodumbaradi ghanavati’ and ‘Ayorajadi lepa’ are undertaken, which are with Switraghna and Varnaya properties.

MATERIAL AND METHODS
The methods adopted in the study are discussed as under.

PLAN OF STUDY
An open label clinical trial was conducted, where the patients were given treatment with specific duration with every 5 days follow up. Oral corticosteroids were withdrawn at least 4 weeks before commencement of trial. Specific instructions on diet and life style modifications were advised to the patients. Institutional Ethics Committee (IEC) approval was obtained and written consent was taken from the patients prior to the initiation of the study.

SOURCE OF DATA:-
a) Patients suffering from Switra are selected from. Dept of Kayachikitsa OPD of Y.M.T Ayurvedic Medical College and Hospital by Preset Inclusion and exclusion criteria.
b) Literary: - Literary aspects of study are collected from classical Ayurvedic and contemporary texts and updated with recent Medical Journals.

DIAGNOSTIC CRITERIA: Shweta varna mandalas with or without other features of switra

INCLUSION CRITERIA:-
1. Patients with classical symptoms of Switra as explained in Ayurvedic classics and diagnosed case of Vitiligo according to the contemporary diagnostic system are included

EXCLUSION CRITERIA:-
1. Patients below 10 years irrespective of sex are excluded.
2. Patients above 60 years of age, irrespective of sex are excluded.
3. Pregnant women and lactating women are excluded.
4. Patients suffering from other systemic disease are excluded.
5. Patients with Burnt areas are excluded.
6. The patches over lips and mouth angulars are excluded.
7. The genital area patches are excluded.

DRUG REVIEW

In the present study the drug for study is - Kakodumbaradi Ghanavati internally and Ayorajadilepa externally possess the following proportions in it.

1) The combination and proportion of Kakodumbaradi Ghanavati is as follows. TABLE NO 1
2) The combination and proportion of Ayorajadilepa is as follows TABLE 2

All the drugs are well identified and collected from local areas. Good manufacturing practice are followed for the preparation of Yogas. The Kakodumbaradi kwatha which is mentioned in kwatha kalpana is taken in the form of Ghanavati because of its palatability form.

POSOLOGY

Administration of Drug:

Internally Kakodumbaradi Ghanavati 2 tabs of 500 mg thrice daily after the food with water

Externally Ayorajadi lepa Q.S. rubbed in water to paste and applied all over the effected skin for 30 minutes exposed in the sun light.

Follow up: 15 days

ASSESSMENT OF RESULT

Subjective and objective parameters will be assessed for result.

1) SUBJECTIVE PARAMETER: Signs and symptoms as designed in classical texts

1. Rukshata: becoming skin dryness at depigmented surface is identified as different grades are as follows –
   Grade 0 – Normal skin dryness
   Grade 1 – Mild
   Grade 2 – Moderate
   Grade 3 – Severe

2. Parushata: becoming skin roughness at depigmented surface is identified as different grades are as follows –
   Grade 0 – Normal skin roughness
   Grade 1 – Mild
   Grade 2 – Moderate
   Grade 3 – Severe

3. Paridwamshi: getting dusty skin at depigmented surface is identified as different grades are as follows –
   Grade 0 – Normal dusty skin
   Grade 1 – Mild
   Grade 2 – Moderate
   Grade 3 – Severe

4. Daha: getting burning sensation of skin at depigmented surface is identified as different grades are as follows –
   Grade 0 – No Burning sensation
   Grade 1 – Mild
   Grade 2 – Moderate
   Grade 3 – Severe

5. Roma Patana: getting hair falling at depigmented surface is identified as different grades are as follows –
   Grade 0 – No hair fall
   Grade 1 – Mild
   Grade 2 – Moderate
   Grade 3 – Severe

6. Kandu: getting itching at depigmented surface is identified as different grades are as follows –
   Grade 0 – No itching
   Grade 1 – Mild
   Grade 2 – Moderate
   Grade 3 – Severe

7. Kleda: getting moisture skin at depigmented surface is identified as different grades are as follows –
   Grade 0 – Normal skin
   Grade 1 – Mild
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Grade 2 – Moderate
Grade 3 – Severe

8. Srava: getting discharge at depigmented surface is identified as different grades are as follows –
Grade 0 – Normal skin
Grade 1 – Mild
Grade 2 – Moderate
Grade 3 – Severe

II) OBJECTIVE PARAMETER

For the assessment of results the following objective parameters were considered:

i) Colour
ii) Margin
iii) Number
iv) VASI score.

To assess the effect number and VASI score were considered as they are without grading before and after treatment. To assess the improvement in colour and margin the following grading were given.

1. Colour: The colour of your skin is due to an interaction between –
   (1) Pigment composition and concentration and
   (2) The dermal blood supply.
   The grades are as follows –
   Grade 0 – Normal skin colour
   Grade 1 – Non-unified normal skin
   Grade 2 – Pigmentation is more than depigmentation
   Grade 3 – Depigmentation equal or more than pigmentation
   Grade 4 – Depigmentation more than pigmentation
   Grade 5 – Complete Depigmentation

2. Margin: margins of the lesions are enumerated as grades are as follows.
   Grade 0 – Normal skin colour attributed
   Grade 1 – Hyper pigmented thick broad width graduated margin
   Grade 2 – Hyper pigmented broad width graduated margin
   Grade 3 – Hyper pigmented well defined

Grade 4 – Hyper pigmented thin edge margin
Grade 5 – Ill defined margin

3. VASI score:

   VASI is to divide the patient into various body regions such as the arms, trunk, legs, hands and feet. Then using the assumption that a palm of the hand is equivalent to 1% of the body surface, the physician determines how much of the skin is affected by Vitiligo. Then the physician determines what percent of the skin is depigmented by referring back to standardized pictures of various degree of pigmentation.

   \[ VASI = \sum \text{value of product of palm units} \times \text{Extent of depigmentation} \]

II) OVERALL ASSESSMENT

Overall assessment of the results are done considering the cumulative effect of subjective and objective parameters. The disease is not totally manageable within the scheduled time, the grades of assessment of results made as under.

TABLE NO. 3

OBSERVATION:
The major improvement was observed in colour and margin of the mandala. The cure rate was observed 6.66% in all the parameter. Well response was found in 33.33% of patients in the colour, 46.66% in the margin, 26.66% VASI score and 0% in the number of mandala. Moderate response was noticed in 36.66% of the patients in the colour.16.66% in the margin and 36.66% in the number and 23.33% in VASI score of mandala. Poor response was observed in 16.66% in the colour, 26.66% in both margin and number and 40% of patients in VASI score of the mandala.

RESULTS

Assessment of subjective parameters in Switra

TABLE NO 4
Assessment of Objective parameters in Switra

TABLE NO.5
The subjective parameters which are considered here show marked response with good percentage of relief. At the objective parameters all has shown the variances on the positive declination in the study.

Results in Switra with Kakodumbaradi Ghanavati and Ayorajadilepa

TABLE 6
Statistical analysis of the clinical and objective parameters Subjective parameter Statistical analysis in Switra with Kakodumbaradi Ghanavati and Ayorajadilepa

TABLE NO. 7
Objective parameter Statistical analysis in Switra with Kakodumbaradi Ghanavati and Ayorajadilepa

TABLE NO. 8

DISCUSSION
The ingredients of Kakodumbaradi Ghanavati act over tridoshas (disorders of the 3 humours) and pacify them.
Kakodumbara: By its tikta (bitter), kashaya (astringent) rasa acts as kapha-pitta shamaka (kapha pitta pacifier), kushtaghna and kandughna. Vidanga: By its ushna veerya warm potency) acts as vata shama-ka. By katu (pungent) rasa and katu vipaka acts as kapha shamaka, and srotoshodhaka (channel purifier). Bakuchi: By its katu, tikta rasa, laghu-rooksha guna, and ushna veerya acts as srotoshodhaka, kapha-pitta shamaka and krimighna.
Ayourajadi lepa having ushana,teekshana and srotoshodaka properties the veerya of lepa reaches the siramuka of swedava srotas and reach the deeper layer twak and it act locally to relive the sanga. By this the samapurana of Bhrajaka pitta takes place and hencenormal function is noticed.

CONCLUSION
1. Some physician emphasizes the topical treatment, others emphasize the internal treatment, but both appear important to the prompt and complete resolution of Switra.
2. The complete cure was observed, 6.66% i.e.2 patients, who are having small lesion and recent onset. The remaining patients were also relieved moderately, from their symptoms.
3. Clinical and statistical analysis reveals that the systemic corrections can be done with internal preparation and the local stimulation by synthesis of melanin through external application may be effective in the management of Switra vis-à-vis Vitiligo.
4. Finally it can be very safely concluded that the above mentioned drug combination has positive role in the management of Switra.

REFERENCES
6. Antony S. Fauci, Dennis L.Kasper ed Harrison’s Principles of internal medicine part2 chapter 54, Mc Graw Hill
Medical publication; 17th edition, pg. 324.


### TABLE NO.1

<table>
<thead>
<tr>
<th>Sr.No</th>
<th>Drug &amp; Botanical Name</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>KAKODUMBAR TWAK (Ficus hispida)⁷</td>
<td>One part</td>
</tr>
<tr>
<td>2</td>
<td>VIDANGA (Emblia ribes)⁸</td>
<td>One part</td>
</tr>
<tr>
<td>3</td>
<td>BAKUCHI BEEJA (Psoralia corylifolia)⁹</td>
<td>One part</td>
</tr>
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</table>

### TABLE NO.2

<table>
<thead>
<tr>
<th>Sr.NO</th>
<th>Drug &amp; Botanical Name</th>
<th>Proportion</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>AYORAJA (Ferrum)¹⁰</td>
<td>One part</td>
</tr>
<tr>
<td>2</td>
<td>KRISHNATILA (Sesamum indicum)¹¹</td>
<td>One part</td>
</tr>
<tr>
<td>3</td>
<td>RASANJANA (beriberi extract)¹²</td>
<td>One part</td>
</tr>
<tr>
<td>4</td>
<td>BAKUCHI BEEJA (Psoralia corylifolia)¹³</td>
<td>One part</td>
</tr>
<tr>
<td>5</td>
<td>AMALAKI (Emblica officinalis)¹⁴</td>
<td>One part</td>
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### TABLE NO.3

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th>COLOR</th>
<th>MARGIN</th>
<th>NUMBER %</th>
<th>IN</th>
<th>VASI SCORE</th>
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</thead>
<tbody>
<tr>
<td>Cured</td>
<td>Normal</td>
<td>Normal or no margin</td>
<td>100</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Well responded</td>
<td>non unified</td>
<td>hyper pigmented thick</td>
<td>more than 75%</td>
<td>more than 75%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>normal skin colour</td>
<td>broad width graduated margin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderately Responded</td>
<td>pigmentation</td>
<td>hyper pigmented broad</td>
<td>more than 50%</td>
<td>more than 50%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>equal to depigmentation</td>
<td>width graduated margin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poorly Responded</td>
<td>depigmentation</td>
<td>hyper pigmented well</td>
<td>less than 50%</td>
<td>less than 50%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>is more than</td>
<td>defined margin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not responded</td>
<td>No pigmentation</td>
<td>No changes in margin</td>
<td>No reduction</td>
<td>No reduction</td>
<td></td>
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</table>

### TABLE NO.4

<table>
<thead>
<tr>
<th>Subjective parameters</th>
<th>Patients Before</th>
<th>Patients After</th>
<th>Patients Changed</th>
<th>Changed %</th>
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<tbody>
<tr>
<td>Rookshata</td>
<td>5</td>
<td>1</td>
<td>4</td>
<td>80</td>
</tr>
<tr>
<td>Parusha</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>Daha</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>Kandu</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>50</td>
</tr>
<tr>
<td>Guruta</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>100</td>
</tr>
</tbody>
</table>

### TABLE NO.5

<table>
<thead>
<tr>
<th>Objective parameters</th>
<th>Mean Before</th>
<th>Mean After</th>
<th>Mean Difference</th>
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</thead>
<tbody>
<tr>
<td>Colour</td>
<td>4.06</td>
<td>1.866</td>
<td>2.0194</td>
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<tr>
<td>Margin</td>
<td>4.133</td>
<td>1.866</td>
<td>2.266</td>
</tr>
<tr>
<td>Number</td>
<td>13.76</td>
<td>9.76</td>
<td>3.99</td>
</tr>
</tbody>
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TABLE NO.6

<table>
<thead>
<tr>
<th>Result</th>
<th>Number of patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cured</td>
<td>2</td>
<td>6.67</td>
</tr>
<tr>
<td>Well Responded</td>
<td>8</td>
<td>26.66</td>
</tr>
<tr>
<td>Moderately Responded</td>
<td>11</td>
<td>36.67</td>
</tr>
<tr>
<td>Poor Responded</td>
<td>8</td>
<td>26.66</td>
</tr>
<tr>
<td>Not Responded</td>
<td>1</td>
<td>3.34</td>
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<tr>
<td>Total</td>
<td>30</td>
<td>100</td>
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</table>

TABLE NO. 7

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<tr>
<th>Subjective parameters</th>
<th>Mean</th>
<th>SD</th>
<th>SE</th>
<th>t-Value</th>
<th>p-Value</th>
<th>Significance</th>
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</thead>
<tbody>
<tr>
<td>Rookshata</td>
<td>0.266</td>
<td>0.52</td>
<td>0.095</td>
<td>2.804</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
<tr>
<td>Parusha</td>
<td>0.066</td>
<td>0.365</td>
<td>0.066</td>
<td>1.0</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
<tr>
<td>Daha</td>
<td>0.1</td>
<td>0.402</td>
<td>0.073</td>
<td>1.36</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
<tr>
<td>Kandu</td>
<td>0.3</td>
<td>0.65</td>
<td>0.118</td>
<td>2.523</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
<tr>
<td>Guruta</td>
<td>0.13</td>
<td>0.434</td>
<td>0.079</td>
<td>1.68</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
</tbody>
</table>

HS = Highly Significant, ID = Insufficient Data

TABLE NO.8

<table>
<thead>
<tr>
<th>Objective parameters</th>
<th>Mean</th>
<th>SD</th>
<th>SE</th>
<th>t-Value</th>
<th>p-Value</th>
<th>Significance</th>
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<tr>
<td>Colour</td>
<td>2.2</td>
<td>0.961</td>
<td>0.175</td>
<td>12.53</td>
<td>&lt;0.001</td>
<td>HS</td>
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<tr>
<td>Margin</td>
<td>2.26</td>
<td>1.04</td>
<td>0.191</td>
<td>11.84</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Number</td>
<td>4.06</td>
<td>5.686</td>
<td>1.03</td>
<td>3.94</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>VASI</td>
<td>0.296</td>
<td>0.435</td>
<td>0.079</td>
<td>3.72</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
</tbody>
</table>

HS = Highly Significant

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