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

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ABSTRACT

OBJECIVE:

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 prabha*va 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* faternity 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*[1]. *Swith* means whiteness and *Rik* is suffix of *'Shweta' Dhatu. Shabdakalpadruma* defined the term for white colored object[2]. 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 macules. These patches are more common in sun-exposed areas including the hands, feet, arms, face and lips. [4] 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.[5] 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 macules which are flush on to the surface.[6]. 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 ghanvati'* 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, irrespec tive 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 angula tions 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 followsTABLE 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.

I) 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

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 parameter were consider

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

To assess the effect number and VASI score were consider 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 margin
Grade 4 – Hyper pigmented thin edge margin
Grade 5 – Ill defined margin

3. VASI score:[16]

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

$$\text{VASI} = \frac{\text{Sum of value of product of palm units X Extent of depigmentation}}{\text{Total Body surface area}}$$

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 *mandal*

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 shamaka*. 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.*

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TABLE NO.1

Sr.No	Drug & Botanical Name	Proportion
1	*KAKODUMBAR TWAK* (*Ficus hispida*)[7]	One part
2	*VIDANGA* (*Emblia ribes*)[8]	One part
3	*BAKUCHI BEEJA* (*Psoralia corylifolia*)[9]	One part

TABLE NO. 2

Sr.NO	Drug & Botanical Name	Proportion
1	*AYORAJA* (*Ferrum*)[10]	One part
2	*KRISHNATILA (Sesamum indicum)*[11]	One part
3	*RASANJANA (beriberi extract)*[12]	One part
4	*BAKUCHI BEEJA (Psoralia corylifolia)*[13]	One part
5	*AMALAKI (Emblica officinalis)*[14]	One part

6	*BHRINGARAJA (Eclipta alba)*[15]	One part

TABLE NO.3

ASSESSMENT	COLOR	MARGIN	NUMBER IN %	VASI SCORE
Cured	Normal	Normal or no margin	100	0
Well responded	non unified normal skin co-lour	hyper pigmented thick broad width graduated margin	more than 75% reduction	more than 75% reduction
Moderately Re-sponded:	pigmentation equal to depig-mentation	hyper pigmented broad width graduated mar-gin	more than 50% reduction	more than 50% reduction
Poorly Re-sponded:	depigmentation is more than pigmentation	hyper pigmented well defined margin	less than 50% reduction	less than 50% reduction
Not responded	No pigmentation developed	No changes in margin	No reduction	No reduction

TABLE NO.4

Subjective pa-rameters	Patients Before	Patients After	Patients Changed	Changed %
Rookshata	5	1	4	80
Parusha	2	1	1	50
Daha	2	1	1	50
Kandu	4	2	2	50
Guruta	1	0	1	100

TABLE NO.5

Objective parame-ters	Mean Before	Mean After	Mean Difference
Colour	4.06	1.866	2.0194
Margin	4.133	1.866	2.266
Number	13.76	9.76	3.99

VASI	1.174	0.579	0.595

TABLE NO.6

Result	Number of patients	Percentage
Cured	2	6.67
Well Responded	8	26.66
Moderately Responded	11	36.67
Poor Responded	8	26.66
Not Responded	1	3.34
Total	30	100

TABLE NO. 7

Subjective parameters	*Mean*	*SD*	*SE*	*t-Value*	*p-Value*	*significance*
Rookshata	*0.266*	*0.52*	*0.095*	*2.804*	*>0.05*	*NS*
Parusha	*0.066*	*0.365*	*0.066*	*1.0*	*>0.05*	*NS*
Daha	*0.1*	*0.402*	*0.073*	*1.36*	*>0.05*	*NS*
Kandu	*0.3*	*0.65*	*0.118*	*2.523*	*>0.05*	*NS*
Guruta	*0.13*	*0.434*	*0.079*	*1.68*	*>0.05*	*NS*

HS = Highly Significant, ID = Insufficient Data

TABLE NO.8

Objective parameters	Mean	SD	SE	t-Value	p-Value	Significance
Colour	2.2	0.961	0.175	12.53	<0.001	HS
Margin	2.26	1.04	0.191	11.84	<0.001	HS
Number	4.06	5.686	1.03	3.94	<0.001	HS
VASI	0.296	0.435	0.079	3.72	<0.001	HS

HS = Highly Significant

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