



## “EFFICACY AND SAFETY ASPECT OF DHĀTRYĀDI KVĀTHA WITH BĀKUCĪ BĪJĀ CURNA & AVALGUJA BĪJĀDI LEPA IN THE MANAGEMENT OF ŚVITRA W.S.R. TO VITILIGO –A RANDOMISED CLINICAL TRIAL”

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### ABSTRACT

*Śvitra* - a soul harrowing disease is one among various skin diseases. It is very distressing disease for both the patients and physician. It is a major problem for patients, because of its ugly appearance and presentation of the body, which may disturbs his personal, familial and social life as well as due to long term treatment; while for physician *Śvitra* is troublesome because there is lack of particular remedy for radical cure and its poor prognosis. According to *Āyurveda Bhrājaka Pitta* gets vitiated, which is responsible for normal skin color, leads to white colored skin patches, named as *Śvitra Vyādhi*. According to Modern dermatology, *Śvitra* can be correlated with Vitiligo and Leucoderma. Aims: - To evaluate the efficacy & safety of *Avalguja Bijādi Lepa* with *Dhātryādi Kvātha* in the management of *Śvitra*. Methodology: - Randomized Clinical Trial on 50 patients was conducted at NIA Jaipur for the duration of 3 months. Result: - Statically significant improvements were showed in subjective parameters. Discussion & Conclusion:-*Dhātryādi Kvātha* with *Bākucī Bījā Curna* & *Avalguja Bijādi Lepa* showed good effect on Vitiligo without any serious adverse drug reaction.

**KEYWORDS :** Avalguja Bijādi Lepa, Dhātryādi Kvātha, Śvitra, Vitiligo & Clinical Trial

### INTRODUCTION:-

The word '*Śvitra*' has its root in the Sanskrit word '*Seta*', which means white patch. *Śvitra* means whitish or morbid whiteness of the skin or Vitiligo.<sup>1</sup> *Ācārya Caraka* said that *Kilāsa* has three<sup>2</sup> varieties that are *Dāruṇa*, *Varuṇa* and *Śvitra*. Thus, he has mentioned the word *Śvitra* as a type of *Kilāsa* but later, describing the treatment of disease, the term *Śvitra* mainly used in description.<sup>3</sup> Vitiligo is a progressive disease in which the melanocytes are gradually destroyed causing un-pigmented areas on the skin. It is estimated between 3-4% in India, although an incident as high as 8.8% has also been reported,<sup>4</sup> irrespective of the races especially to dark skinned people. Males and females are equally affected.<sup>5</sup> About half show the disorder before age 20 and most develop it before age 40.<sup>6</sup> Vitiligo on the face is ranked 17th by WHO in world's most Disabling diseases. Vitiligo has been proposed to be a multifactorial disease with genetic susceptibility and environmental factors both thought to play a role.<sup>7</sup> The tyrosinase enzyme is encoded by the TYR gene, which is not a component of the immune system, but is an enzyme of the melanocyte that catalyzes melanin biosynthesis, and a major auto-antigen in generalized Vitiligo<sup>8</sup>. Due to the chronic nature of disease, long-term treatment, lack of uniform effective therapy and unpredictable course of disease is usually very demoralizing for patients. In modern science PUVA (Psoralen + Ultra Violet) an exposure therapy and corticosteroids are mainly used for treatment of disease<sup>9</sup> but therapies have so many harmful side effects. So it is really needed to find a safe, easier, less complicating, cost effective and fruitful approach for the management of disease, and world is expecting some beneficial and useful remedies from the *Āyurveda*.

### AIMS AND OBJECTIVES:-

To evaluate the efficacy & safety of *Avalguja Bijādi Lepa* with *Dhātryādi Kvātha* in the management of *Śvitra*

### MATERIAL AND METHODS:-

**1. Selection of patients-** The patients for the clinical study were selected from O.P.D. and I.P.D. of NIA *Ārogyaśālā* Hospital. Selection was carried out on the basis of relevant history, signs, symptoms and laboratory investigations suggestive for the disease *Śvitra* (Vitiligo). A written information and consent form had been given to the selected patients. The patients were explained about the purpose, procedures and possible side-effects of the trial drugs. Total 58 patients were registered for the study, but 50 patients had completed the trial.

#### 1.1 Criteria for the selection of the patient:

##### A. INCLUSION CRITERIA

1. Patient with the classical sign and symptoms of *Śvitra*.
2. Patients above 18 years and below 70 years of age.
3. Patients belonging to either gender.

##### B. EXCLUSION CRITERIA

- The patient suffering from systemic disorders.
- The pregnant women and lactating mother.
- Patient less than 18 years and above 70 years of age.
- All other de-pigmentary disorders.
- Serious cardiac, renal, hepatic diseases, Diabetes mellitus.
- Patches due to burning, chemical explosion etc.
- Located at region of *Guhyānga* (genital organ), *Pāñitala* (sole of palm and feet), *Oṣṭa* (lips) and *Sarvānga* (whole body).
- Patches with *Raktaroma* (reddish hair) & *Samāsakta* (coalescent).

### STUDY DESIGN:-

- **CTRI Registration number:-**(CTRI/2019/08/020999)
- **Study type :** Randomized Clinical Study
- **Study design :** Open label
- **Timing :** Prospective
- **End point :** Efficacy and safety
- **Sample Size:** 50
- **Duration of trial:** 3 month
- **Follow up:** 30<sup>th</sup>, 60<sup>th</sup> & 90<sup>th</sup> days,
- **Non-drug follow up** have done at the interval of one month for the period of 3 months.

**1.4 -Ethical consideration:-** Ethics committee approval: Before initiating the study, approval for the study protocol, written informed consent, consent form updates and participant recruitment procedures was obtained from the Institutional Ethics Committee.

**Assessment criteria:** For the purpose of assessment, a detailed research proforma will be made incorporating various parameters like *Daśavidha Parīkṣā*, *Aṣṭavidha Parīkṣā* etc. Assessment will be done every 30 days during the entire study period.

### Subjective parameters:-

- Colour of patches: - *Svetābha* (*Raktabha*) & *Kamalapatravata* (Lotus petal like) are indicating colour of patches, *Maṅḍalotpatti* (Beginning of patch), *Rukṣta* (Dryness), *Paridhvaṁsī* (*Roma Vidhvaṁsī*), *Saparidaha* (Burning sensation), *Snigdha* (Unctuousness), *Bahal* (Thickness), *Kaṇḍu* (Itching), Affected area, Size of patches & Chronicity of the patches

### Objective parameters-

- Haematological – CBC, Biochemistry – RBS, TSH, T3 and T4

### Preparation of the Trial Drugs and Dose-

*Avalguja Bijādi Lepa*<sup>10</sup> for local application and *Dhātryādi Kvātha*<sup>11</sup> with *Bākucī Bījā Curna* for internal use.

Dose: *Avalguja Bijādi Lepa* use for local application two-time in a day and *Dhātryādi Kvātha* (40ml) with *Bākucī Bījā Curna* (1gm) B.D.

A special **SCORING PATTERN** was adopted for the symptoms as follows

**1. Śvetābha ,Raktabha & Kamalapatravata ( Lotus petal like) indicate color of patches**

Sr. N	Color of the patches	Score
1	Normal skin colour	0
2	Red colour	1
3	White to reddish	2
4	Red to whitish	3
5	White	4

**2. Maṇḍala (Number of patches Countable/Uncountable):-**

Sr. N	Number of patches	Score
1	No Maṇḍala	0
2	1-3	1
3	4-6	2
4	7-10	3
5	More than	4

**3. Rukṣatā (Dryness):-**

Sr. N	Rukṣatā (Dryness)	Score
1	No dryness	0
2	Occasional dryness without winter season	1
3	Visible dryness, mild dull white streaks after scratching on the skin which disappears after sometime.	2
4	Dryness/roughness, bright white streaks on the skin remaining for a considerable time.	3
5	Dryness/roughness and criss-cross-visible cracking of skin.	4

**4. Paridhvaṁsī (Roma Vidhvaṁsī):-**

Sr. N	Paridhvaṁsī (Roma Vidhvaṁsī)	Score
1	Absent	0
2	Present	1

**5. Sapidāha - (Burning sensation)**

1	No Paridāha	0
2	Mild Paridāha	1
3	Moderate Paridāha	2
4	Severe Paridāha	3

**6. Snigdha:-**

1	No Snigdha	0
2	Mild Snigdha	1
3	Moderate Snigdha	2
4	Severe Snigdha	3

**7. Bahal: (Thickening of skin lesion)**

1	No Bahal	0
2	0-Mild thickening	1
3	1-Moderate thickening	2
4	Very thick	3
5	2-Very thick with in duration	4

**8 Kaṇḍū (Itching)**

1	Never	0
2	Rarely	1
3	Sometimes	2
4	Often	3
5	All the times	4

For the assessment of the involvement of body surface area, the Rule of Nine described in the forensic medicine was used with certain modifications. The whole body was scored as per the text as per the rule of Nine, but looking to the nature of the disease, score was further specified to the organs as follows.

- Posterior surface and anterior surface of head and neck= 9
- Anterior and posterior surface of forearms 18+18=36
- Anterior and posterior surface of trunk= 18
- Anterior and posterior and surface of feet, legs and buttocks 18+18=36
- Perineum including anus and uro-genetical =1

**9. Affected area**

Sr. N	Percentage of affected area	Score
1	1 %	1
2	2%	2
3	3%	3
4	4%	4
5	More than 4%	5

**10. Size of patches:**

Sr. N	Size of Mandal (patches)	Score
1	Less than 1 cm	1
2	1 -2 cm	2
3	2-3 cm	3
4	3-4 cm	4
5.	More than 4 cm	5

**11. Chronicity of the patches:**

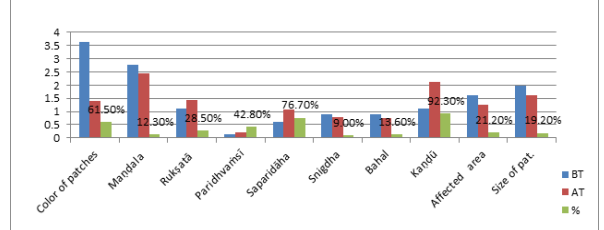
Sr. N	Chronicity of the patches	Score
1	Less than 1 year	1
2	1-3 years	2
3	4-7 years	3
4	More than 7 years	4

**RESULTS (EFFECT OF THERAPY)**

**Table no-1:- Showing the inner group comparison effect of drugs on subjective parameters (Wilcoxon matched paired single ranked test)**

Subjective parameters	Mean		Diff.	Diff. %	S.D.	S.E.	W	P Value	Result
	BT	AT							
Color of patches	3.64	1.40	2.24	61.5 %	0.87	0.12	1225	<0.0001	ES
Maṇḍala ( Number of patches)	2.78	2.44	0.34	12.3 %	0.87	0.12	273	0.0051	VS
Rukṣatā (Dryness)	1.12	1.44	-0.32	28.5 %	0.68	0.09	-200	0.0028	VS
Paridhvaṁsī (Roma Vidhvaṁsī)	0.14	0.20	-0.06	42.8 %	0.42	0.06	-15	0.2129	NS
Sapidāha - (Burning sensation)	0.60	1.06	-0.46	76.7 %	0.76	0.10	-240	0.0001	ES
Snigdha (Unctuousness)	0.88	0.80	0.08	9.0 %	0.60	0.08	30	0.2106	NS
Bahal: (Thickening patches)	0.88	0.76	0.12	13.6 %	0.60	0.09	57	0.1290	NS
Kaṇḍū (itching)	1.10	2.12	-1.02	92.3 %	1.09	0.15	-628	<0.0001	ES
Affected area	1.60	1.26	0.34	21.2 %	0.60	0.08	221	0.0010	VS
Size of patches	1.98	1.60	0.38	19.2 %	0.43	0.06	78	0.0002	ES

**Table no-1:- Showing the inner group comparison effect of drugs on subjective parameters**

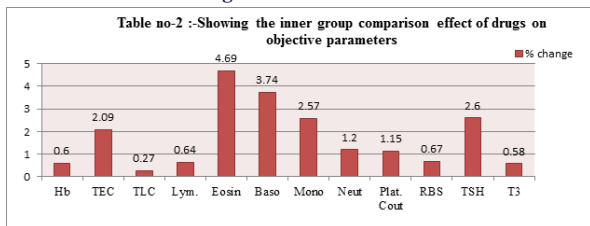


**Table no-2:- Showing the inner group comparison effect of drugs on objective parameters in Group-B (Paired t test)**

Objective parameters	Mean		Diff.	Diff. %	S.D.	S.E.	T	P Value	Result
	BT	AT							
Hemoglobin	12.87	12.94	-0.07	0.60	0.85	0.12	0.63	0.2672	NS
TEC	4.30	4.40	-0.09	2.09	0.44	0.06	1.53	0.0667	NS
TLC	7194	7175	19	0.27	335.7	47.4	0.40	0.3438	NS

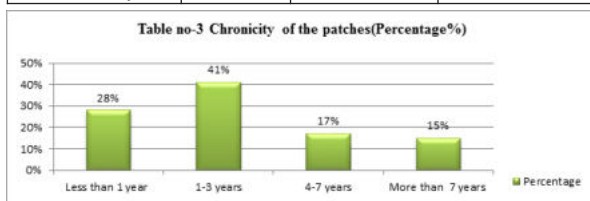
Lymphocyte	31.3	31.1	0.2	0.64	0.42	0.06	0.36	0.358	NS
Eosinophils	3.62	3.79	-0.17	4.69	0.52	0.07	1.41	0.215	NS
Basophiles	1.07	1.03	0.04	3.74	0.28	0.04	0.99	0.162	NS
Monocytes	6.59	6.41	0.17	2.57	0.71	0.10	1.06	0.143	NS
Neutrophils	57.02	56.34	0.68	1.2	2.38	0.33	0.67	0.224	NS
Platelet Count	2.59	2.56	0.03	1.15	0.66	0.09	0.34	0.367	NS
RBS	91.04	91.65	-0.61	0.67	4.17	0.59	1.03	0.153	NS
TSH	1.92	1.97	-0.05	2.60	0.25	0.03	0.19	0.424	NS
T3	150.16	151.02	0.86	0.58	9.30	1.31	0.21	0.420	NS
T4	8.06	7.99	0.07	0.87	0.66	0.09	0.80	0.211	NS

TEC=Total Erythrocyte Count, TLC= Total Leucocytes Count& RBS=Random Blood Sugar



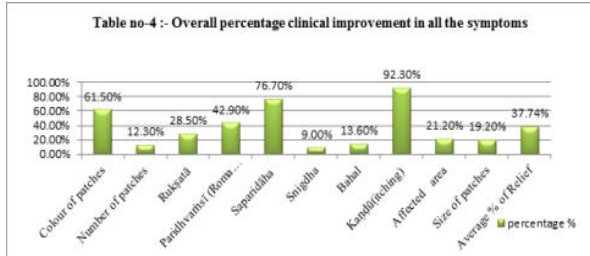
**Table no-3:-Scoring compliant with Chronicity wise distributions- Chronicity of the patches remains same before& after treatment.**

Chronicity	Scoring	No. of Patients	Percentage
Less than 1 year	1	13	28%
1-3 years	2	21	41%
4-7 years	3	08	17%
More than 7 years	4	08	15%



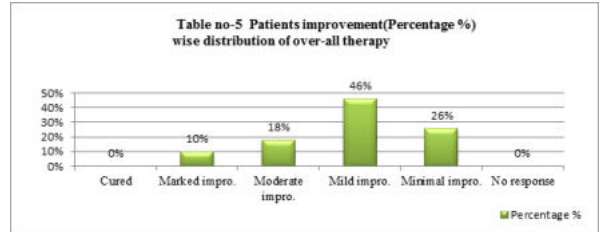
**Table no-4:-Showing the overall clinical improvement in all the symptoms**

Symptoms	Group	
	%	Impression
Colour of patches	61.5%	Moderate improvement
Number of patches	12.3%	Minimal improvement
Rukṣatā	28.5%	Moderate improvement
Paridhvaṁsī (RomaVidhvaṁsī)	42.9%	Moderate improvement
Saparidāha	76.7%	Marked improvement
Snigdha	9.0%	Minimal improvement
Bahal	13.6%	Minimal improvement
Kaṇḍū(itching)	92.3%	Marked improvement
Affected area	21.2%	Minimal improvement
Size of patches	19.2%	Minimal improvement
Average % of Relief	37.74%	



**Table no-5:- Showing Patients improvement wise distribution of over-all therapy**

Group		Result
No. of patients	Percentage	
00	0%	Cured
05	10%	Marked improvement
09	18%	Moderate improvement
23	46%	Mild improvement
13	26%	Minimal improvement
00	0%	No response



**Evaluation of Adverse Events (Safety Evaluation):**

There were no any SAE reported in the study.

**Table 6: Assessment of safety aspect**

Safety	Number of patients	Percentage (%)
Excellent safety	10	20%
Good overall safety	20	40%
Fair safety	12	24%
Poor safety	03	6%
Adverse events	05	10%



**Table no-7:- Assessment of Adverse Events**

Total AE	Unrelated	Unlikely	Possible	Probable	Definite
05	02	0	0	03	0

There were no any SAE reported in the study.

**DISSUCTION & CONCLUSION:-**

**A. Demographic profile**

**1. Prevalence of Age:-** In the study maximum 44% patients were 18-28yrs age Group Mean age at onset was reported to be within the first three decades in studies by Zhanget al.<sup>12</sup>

**2. Prevalence of Gender:-** In the study maximum 54% were female and 46% were male were participated. Gender has no direct link to Vitiligo. But here reported data showed that female patients were more prone to white patches on skin Female prevalence was also reported in earlier studies from Rome<sup>13</sup>, Tunisia<sup>14</sup>, India<sup>15</sup> (Gujarat)<sup>16</sup> and in some of the worldwide pooled data.<sup>17</sup>

**3. Prevalence of Family History:-** 8% patients have reported with family history. Two earlier Indian studies, reported much higher rates (20.4%<sup>18</sup> & 11.31%<sup>19</sup>).

**4. Prevalence of Marital Status:-** Maximum 66% were marriage, Probable reason may be that in study our age criteria was more than 18 years (18-70 yrs).

**5. Prevalence of Religion, Socio-economic status, Occupation, Addiction:-** Maximum 82% patients were from Hindu community due to Hindus are found in abundance in research area, maximum 56% patients were upper middle class. Max. 34% were doing private job & max. 74% patients were addition with tea/coffee. There are no correlation were reported with Vitiligo.

**6. Prevalence associated with autoimmune diseases:-**Total 9 patients (18%) were reported with autoimmune diseases. Max. 5 patients (10%) were associated with thyroid disorder. We elicited that the prevalence of auto-immune diseases (especially thyroid disorders) was significantly higher in Vitiligo patients. This is also in concurrence with previous studies.<sup>20</sup> Several authors reported a significantly increased prevalence of thyroid diseases in Vitiligo patients.<sup>21</sup>

**7. Prevalence of most affected body part:-** Maximum 40% patients were reported Vitiligo on Head and Neck. Head and neck was the most common initial site of onset (n=36, 36.0%)<sup>22,23</sup>

### B. Effect of therapy on symptomatology:-

1. Statistically considered **extremely significant** result was found in colour of patches (**61.5% & P<0.0001**), *Saparidāha*-(burning sensation) (**76.7% & P=0.0001**), *Kandū* (itching) (**92.3% & P<0.0001**) and in size of patches (**19.2% & P=0.0002**).
2. Statistically **very significant** result was found in number of patches (**12.3% & P=0.0051**), *Rukṣatā* (**28.5% & P=0.0028**) and affected area (**21.2% & P=0.0010**).
3. Statistically **not-significant** result was found in *Paridhvamsī* (*Roma Vidhvamsī*) (**42.8% & P=0.2129**), *Snigdha* (**9.0% & P=0.2106**), *Bahal* (**13.6% & P=0.1290**).

*Śvitra* is *Rakta Pradoṣaja Tridoṣaja Vyadhi*: *Kapha Doṣa* is the most dominant *Doṣa* in *Śvitra*. In *Dhātryādi Kvātha Amalākī & Khadira* are main integrates. *Amalā*<sup>24</sup> are *Amla*, *Kaṣāya*, *Madhura*, *Tikta*, *Kaṭu Rūkṣa Laghu Tridoṣajit Vṛṣya Rasāyana*. *E. officinalis* has strong skin photo-protective effects through its ability to quench reactive oxygen species generated by UVB irradiation due to antioxidant activity related to UV protection<sup>25</sup>. *Khadira* (*Acacia catechu*)<sup>26</sup> are *Kaṣāya*, *Tikta*, *Kaṭu* – *Vipāka*, *Kapha Pittahara*, *Raktaśodhaka*, *Kuṣṭhaghna*. *Acharya Charaka* mention *Khadira* and *Amalā* in *Kuṣṭhaghna mahakaṣāya*.<sup>27</sup> *Bākucī*:-Properties and actions<sup>28</sup> - *Kaṭu*, *Tikta*, *Rūkṣa*, *Laghu*, *Uṣṇa*, *Kaṭu* (*Vipāka*), *Vraṇāpaha Slesmārapittanut*. All most our *Ācāyas* mentioned *Bākucī* as a drug of choice in *Kilāsa* (*Śvitra*).

The seed contain psoralen, isopsoralen, bavachinin. A mixture of psoralen and isopsoralen, in a ratio of 1:3, is recommended for topical application in leucoderma.<sup>29</sup> In *Avalguja Bijādi Lepa* all most ingredients are *Kaṭu*, *Tikta*, *Rūkṣa*, *Laghu*, *Uṣṇa* (*Viryā*) *Kaṭu* (*Vipāka*). Actions- *Slesmārapittanut* (*Bākucī*) *Raktadoshahara Kuṣṭha*, *Kaṇḍu-Nasaka* (*Haratāla*) *Srotośodhani*, *Vraṇya* (*Manahṣila*), which lead to *Samprāpti Vighatana* of *Śvitra*. Above properties of both *Yogas* are effective acts to control the symptoms of *Śvitra*.

### C. Effect on laboratory parameters:-

1. Statistically considered **not significant** result was found in **Hemoglobin** (0.60% & P=0.2672), **TEC** (2.09% & P=0.0667), **TLC** (0.27% & P=0.3438), **Lymphocyte** (0.64% & P=0.3581), **Basophils** (3.74% & P=0.1623), **Eosinophils** (4.69% & P=0.2152) **Platelet Count** (1.15% & P=0.3675), **RBS** (0.67% & P=0.1532), **TSH** (2.60% & P=0.4245), **T3** (0.58% & P=0.1532), **T4** (0.87% & P=0.2118), **Monocytes** (2.57% & P=0.0431) and **Neutrophils** (1.2% & P=0.0242). *Dhātryādi Kvātha* with *Bākucī Bijā Curna* & *Avalguja Bijādi Lepa* are not significant effect above laboratory parameters.

### CONCLUSION:-

The study is overall concluded that the *Avalguja Bijādi Lepa* for local application and *Dhātryādi Kvātha* with *Bākucī Bijā Curna* for internal use are effective in reducing subjective variables of *Śvitra* (Vitiligo).



Before Trial

After Trial

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