

## ***OPEN CONTROLLED CLINICAL STUDY EVALUATING THE THERAPEUTIC EFFECT OF BAKUCHI RASAYANA IN SHWITRA***

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### ABSTRACT

**Objective:** To evaluate the therapeutic efficacy of *Bakuchi Rasayana* in the remission of the symptoms of *Shwitra/Vitiligo*, to evaluate the therapeutic efficacy of *Shashilekha Vati* in the remission of the symptoms of *Shwitra/Vitiligo* and to compare the effect of *Bakuchi Rasayana* and *Shashilekha Vati* in bringing symptomatic relief in the patients of *Shwitra/Vitiligo*. **Design:** Open controlled clinical-study with pre and post-test design. **Setting:** I.P.D. of Shri Dharmasthala Manjunatheshwara College of Ayurveda & Hospital, Udupi. **Participants:** 27 patients diagnosed with *Shwitra*. **Interventions:** The patients selected were randomly divided into 2 groups by adapting open labelled randomization method. *Bakuchi Rasayana* Group: 15 patients were treated with *Bakuchi Rasayana* for a period of 30 days with the *anupana* of 24 ml of *Gomutraarka* during morning in empty stomach for 30 days. *Shashilekha vati* Group: 12 patients were treated by orally administration of Tab. *Shashilekha vati*, 125 mg, tid with *anupana* of *Bakuchi taila* 10 ml, during morning in empty stomach for 30 days. **Main outcome measures:** The response following the intervention was assessed every month by adapting the scoring method for colour, size, number, percentage of body area involved. Further the changes are assessed by adapting VETI score. Finally the changes observed at completion of the treatment were subjected to paired t test, unpaired t test to know the statistical significance. **Results:** *Bakuchi Rasayana* and *Shashilekha Vati* are effective in the remission of the symptoms of *Shwitra* as evidenced by statistically significant reduction in the symptom score of various subjective and objective parameters. **Interpretation & Conclusion:** *Bakuchi Rasayana* and *Shashilekha Vati* are effective in the remission of the symptoms of *Shwitra* as evidenced by statistically significant reduction in the symptom score of various subjective and objective parameters. The effectiveness of the *Bakuchi Rasayana* is supreme in comparison to that of *Shashilekha Vati* as evidenced by the various outcome measures and the statistical analysis shows that it is significant.

**Keywords:** *Shwitra, Bakuchi Rasayana, Shashilekha Vati, Vitiligo.*

## INTRODUCTION

In Ayurvedic classics *Kushta* is considered as an important disease and is categorized as *Maharoga*. *Shwitra* is one of the varieties of *Kushta*<sup>5</sup> and even the causes of the *Kushta* are considered as etiological for this condition as well. This disease of dermis can spoil the beauty of skin and pose minor and major cosmetic problem. The lesions of *Shwitra* being dry and also non-infectious, thus differs from the *Kushta* in general. The disease is characterized by invariable morbidity of all the three *dosha* afflicting *rasa, rakta, twak* and *mamsa dhatu*<sup>6</sup>. *Shwitra* is a chronic deteriorating skin disorder which is in reality challenge to the whole medical field as the complete cure to this illness is a remote possibility. No doubt the illness is not fatal, but it poses embarrassment and inferiority complex to the person affected. More to add, the person having *Shwitra* will feel that they are separated from the society and get depressed psychologically and our society also has a contemptuous opinion regarding these persons. *Shwitra* is also a variety of *Kushta*, which can spoil the beauty of the skin, is characterized by whitish depigmentation. *Shodhana* and *Shamana* measures are proved to be efficacious in the treatment of *Shwitra*. The drug taken for the present study *Bakuchi Rasayana* is one of the *yogas* mentioned by *Acharya Sushruta* in *Medhavyushkamiya Rasayana Chikitsa*. It basically contains *Bakuchi, Guda* and *Gritha* and *Gomutraarka* as *Anupana*. *Samshodhana* is mentioned as a modality, which is followed as a pre requisite for administration of *Rasayana*. Here *sadhya shodhana* has been carried out with *Trivrit leha* for *Koshta shodhana*, as a pre

requisite for *Rasayana chikitsa*. *Bakuchi choorna* was administered in the form of capsule in the dose of 24 gm in the morning empty stomach with *Gomutraarka* as *Anupana* (24ml)<sup>8</sup>.

## OBJECTIVES

1. To evaluate therapeutic effect of ***Bakuchi Rasayana*** in reducing the symptoms of *Shwitra*.
2. To evaluate the therapeutic effect of ***Shashilekha vati*** in reducing the symptoms of *Shwitra*.
3. To compare the effect of ***Bakuchi Rasayana*** and ***Shashilekhavati*** in the reducing the symptoms of *Shwitra*.

## MATERIALS AND METHODS

### STUDY DESIGN

Open controlled clinical study with pre-test and post-test design.

### SOURCE OF DATA

27 patients diagnosed as *Shwitra/Vitiligo* fulfilling the diagnostic/ inclusion and exclusion criteria were taken for study from OPD and IPD of SDM Ayurveda Hospital, Udupi, Karnataka.

### DRUG

The cellulose capsules each containing 500 mg powder of *Bakuchi, Manshila* and ingredients of *ShashilekhaVati* were obtained from SDM Ayurveda Pharmacy Udyavara, Udupi.

### METHOD OF COLLECTION OF DATA

A special proforma was prepared incorporating all the clinical manifestation and assessment criteria of the Vitiligo / Shwitra. Complete clinical data was collected from all the selected patients as per the proforma before the intervention and every week following this until the completion of the study. The selected patients were randomly divided into two groups as Group *Bakuchi Rasayana* (BR) and Group *ShashilekhaVati* (SV). Randomization is done by adapting permuted blocked randomization method. Results obtained were statistically analysed by adapting the paired t test.

#### DIAGNOSTIC CRITERIA

- Must have cardinal symptom of *Shwitra* i.e. visible de-pigmented macules.
- Absence of swelling and scaly lesions in the dermis
- Circumscribed de-pigmented patches with hyper pigmented borders
- Normal tactile sensation.

#### INCLUSION CRITERIA

- Patients fulfilling the criteria of diagnosis irrespective of sex or creed.
- Age 16 to 70 years.
- Written informed consent.

#### EXCLUSION CRITERIA

- Chronicity more than 10 years.
- Spread more than 50% of the body surface.
- Age < 16 and > 70 years
- Patient with any other systemic illness like diabetes mellitus, IHD.
- Burnt areas

#### ASSESSMENT CRITERIA

- Symptoms of *Shwitra*

- VETI<sup>9</sup> (Vitiligo Extent Tensity Index) for evaluation.

#### SATSTICAL ANALYSIS:-

- The results obtained were subjected to statistical analysis using Stat Graph Pad 3 software.
- Paired t-test was used for comparing the results within the control and trial group.
- Student t- test was used for comparing the results between the control and trial group.

#### ETHICAL CLERANCE

Ethical clearance was obtained through the ethical committee formulated in the institution. Reference number-SDMCAU/ACA-49/EC46/14-15. Date-23/4/2015

#### INTERVENTION

##### Group *Bakuchi Rasayana* (Group BR)

- For initial seven days the patients was treated with *Nityavirechana* by oral administration of *Trivritleha* in a dose 12 g in empty stomach in the morning.
- From day 8 to 38, *Bakuchi Rasayana* were orally administered in a dose of 24 gm AC in the morning. 24 ml of *Gomutraarka* was given as *anupana* in these patients.

##### Group *Shashilekhavati* (Group SV)

- The patients in this group were orally treated with *Shashilekhavati* in a dose of 125 mg tid for 30 days. 12 ml of *Bakuchitaila* was given as *anupana*.

#### INVESTGATION

Blood –TC, DC, ESR, Hb%, RBS<sup>10</sup>

#### RESULTS & OBSERVATIONS

Among the 27 patients maximum number of the patients, 11(36%) were between the age

group of 36-55 years, against minimum number of 7 (29%) patients in age group 16-35 years and 78% of the patients belonged to Hindu Religion, 22% of patients belonged to Muslims. Majority of the patients comprising 37% were Primary school and 7% were higher school, 26% patients were junior school, 30% patients were Graduation. Among the 27 patients 37.04% patients were male and 62.96% were females. Majority of the patient belonged to upper middle class i.e. 67% were Middle class, 18% were Upper class, 15% patients were Lower class. Among the 27 patients 19% patients were Students and 22% were Employee, 33% were Home Maker, 26% patients were Businessman. 56% of the patients had the dietary habit of taking mixed diet, and 44% patients were Vegetarian. Out of 27 patients 22% were smokers and other 78% had no addiction. Majority of the patients belongs to 52% *Pittakapha* Prakruti, 41% of patients belonged to *VataKaphaPrakruti*, 7% of the patients belonged to *VataPittaPrakruti*. 74% patients recorded *Madhyamasamhnana*, 19% patients belonged to *Avara Samhanana*, 7% of the patients belonged to *PravaraSamhanana*. Among 27 patients, 0% of the patients belonged to *Pravara*, 81% of patients belonged to *Madhyam*, 19% patients belonged to *Avara*. 59% of patients had *Madhyama AbhyavaharanaShakti*, 56% of patients had *Madhyama JaranaShakti* and 62% of the patients had *AvaraVyayamaShakti*.

- **BakuchiRasayana Group** –It is found that initial mean score on *Twak vaivarnyata* which was 3.00 and reduced to 1.66 after the treatment, thus recording a remission by 44.3%. The initial mean score on *Twak Rukshata* which was 0.66 reduced to 0.26

after the treatment, thus recording a remission by 60.6%. The initial mean score on *Romavivarnata* which was 2.53 reduced to 1.40 after the treatment, thus recording a remission by 44.6%. The initial mean score on Body Region which was 3.33 and reduced to 2.46 after the treatment, thus recording a remission by 25.8%. The initial mean score on VETI Score which was 7.84 reduced to 2.44 after the treatment, thus recording a remission by 68.8%.

- **Shashilekha vati Group** –It is found that the initial mean score on *Twak Twakvaivarnyata* which was 3.00 before the treatment was reduced to 2.92, thus recording a remission by 2.33%. Initial mean score on *TwakRukshata* which was 2.33 before the treatment was reduced to 1.58, thus recording a remission by 32.1%. The initial mean score on *Romavivarnata* which was 2.41 before the treatment was reduced to 1.75, thus recording a remission by 27.3%. The initial mean score on Body Region which was 2.91 before the treatment and was reduced to 2.41, thus recording a remission by 17.1%. The initial mean score on Veti Score which was 4.33 before the treatment was increased to 3.80, thus recording a remission by 12.2%.
- Comparison between the groups shows that *BakuchiRasayana* Group had more improvement compared to *Shashilekha vati* Group which was statistically significant.

## DISCUSSION

All the skin diseases in Ayurveda have been described under the heading of *Kushta*, in other words it can be listed as Ayurvedic dermatology. It is not a vis-à-vis correlation but

one can cover up all skin disease under 18 types of *Kushta*. *Twacha* is formed by the *Paka* of *Rakta Dhatu* by its *Dhatvagni*. It consists of seven layers, out of which, *Shwitra* occurs in the *Tamra* layer, which is the fourth layer of the *Twak*. The Disease *Shwitra* is one among various skin diseases characterized by de-pigmented patches, enlarging and becoming more numerous with time. The disease *Shwitra* is *pittapradhanaTridoshajaVyadhi*. According to *Acharya Sushruta*, *Shwitra* occurs in *tamra* the fourth layer of the *twak* and is 1/8<sup>th</sup> of *Vreehi* in its thickness.

As per the symptomatology & pathogenesis and presenting the symptoms like *Shweta-varna*, *Tamravarna*, *Aparisraavi* i.e. non-exudative or non-oozing type of lesion. *Shwitra* can be correlated to Vitiligo in modern science. Vitiligo is a common autoimmune disorder of depigmentation due to loss of melanocyte. Sufferers often have relatives with other organ specific autoimmune disorders. Lesions are often symmetrical and frequently involve the face, hands and genitalia. The hair can also get de-pigmented.

Different modalities are mentioned for the management of *Shwitra* (Vitiligo) like *Shodhana*, *Shamana*, *Vyadhihara Rasayana* and *Bahirparimarjana Chikitsa* are the bottom of principles of treatment for *Shwitra*. Due to specific etiology factor the vitiated *vata*, *pitta*, *kapha*, affecting the *Twak*, *Rakta*, *Mamsa*, *Lasika*, causes whitish discoloration of skin presenting as *Shwitra*. Irrespective of the discomfort, chronic presentation of the disease proved *bahu dosha avastha* and best treated by *Rasayana chikitsa*. *Rasayana chikitsa* that also demands *shodhana* earlier to medication. Hence to eliminate the *dosha* and preparation of patient for *Rasayana chikitsa shodhana* is

mandatory; with this intention *nityavirechana* is accompanied by administration of *Trivritleha* in a dose of 12 gm OD every day for 7 days. By this treatment it observes that patient has passed 3 to 4 episode of loose stool per day with a addition of improved digestive ability. Strong optimal function of GIT is achieved in all the patients by *shodhanachikitsa*. Following the *shodhana chikitsa Bakuchi* is administered in a dose of 24 gm empty stomach in the morning for 30 day with *Gomutraarka* as *anupana*. This large dose of *BakuchiRasayana* is best administered in a limited period of 30 days. *Gomutraarka* is described as best *anupana* even though accretion smell by consumption likely to cause much unconventional but replacement of the same with *Gomutraarka* proved more acceptable in all the patients. Thus all the patients conventionally consume a large dose of *Bakuchi* with *Gomutraarka* as *anupana*. The result proved that all the patients showed a very good improvement, best to moderate improvement in regard to normalization of colour, size, and number of lesion. Remission of *Aruna* colour followed by medication proved the affectation of *Bakuchi* in remission of symptoms of *vata-dosha*. *Tamra* patches are seen in 5 patients also rehabilitated into normal colour indicated efficacy of pacifying *pittadosha*. White discoloration got partially corrected by medication is suggestive of elimination of *kaphadosha*. Thus these changes proved the efficacy of *BakuchiRasayana* in elimination of all three *dosha* which involved in pathology of *Shwitra*. Normalization of colour and reduction in *Rukshata* is the sign of effect of medication on *Lasika*, *Mamsa*, *Meda*, *Rakta*. The medication is given for the duration of 1 month. The test admitted the administration of

the same medication for 6 months. From this is clear that further improvement obtained by the continuation of *Rasayana* as per authentic text.

*Shodhana, Shamana, Rasayana* is the treatment of any disease. Each procedure has its own importance to eliminate the disease. The efficacy of *Rasayana* excels in form of treatment by virtue of its optimal dosage targeting the *samprapthighataka*. *Shamana* medication is difference from *Rasayana* treatment in regards of dose as well as duration of treatment. *Shashilekhavati* in a dosage of 125mg TID with *Bakuchitaila* 12 ml as *anupana*. Though *Bakuchi* is the main components of *Shamanachikitsa*. Total amount of *Bakuchi* and duration of treatment is comparatively is very less. To be more clear 24 gm of *Bakuchi* per day in *Rasayana* dosage. The reduction in the discoloration like *Aruna, Tamra, Shweta*, by medication with *Shashilekhavati* proved in the remission of the symptoms *vata, pitta, kaphadosha* respectively. The study proved that *Rasayanachikitsa* is more affective in comparison to *Shamanachikitsa*. Though that prevails difference in combination *BakuchiRasayana* and *Shashilekhavati*, the major difference is contents in these formulations *Bakuchi* being claimed as drug of choice in *Shwitra*.

Before last it can be said that both the medication are safe effective and used partially in 30 days. At last to say if the same medication is used for longer duration to complete remission of the symptoms is adopted and also justified in *SushrutaSamhita*.

## CONCLUSION

*Bakuchi Rasayana* and *SashilekhaVati* are effective in the remission of the symptoms of

*Shwitra* as evidenced by statistically significant reduction in the symptom score of various subjective and objective parameters. The effectiveness of the *BakuchiRasayana* is supreme comparing to that of *SashilekhaVati* as evidenced by the various outcome measures and the statistical analysis shows that it is significant.

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