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Research Article

CLINICAL EVALUATION OF *SHASHILEKHA VATI* IN THE MANAGEMENT OF *SHVITRA* WITH SPECIAL REFERENCE TO VITILIGO

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ABSTRACT

In Ayurveda, it is described that *Viruddha aahar* is the main etiological factor for so many diseases. *Shvitra* is one of them. This study focuses to develop evidence based support for efficacy of textual reference of *Yogaratnakara* regarding *Shvitraghna* property of *Shashilekha Vati* with *Bakuchi tail* and *Madhu* as *Anupana* with special reference to vitiligo. *Shashilekha Vati* was prepared according to the method mentioned in the classical text of *Yogaratnakara*. The trial was conducted on a sample size of 60 divided in two groups. In the criteria of assessment, measurement of area of lesion, nature of regimentation and degree of regimentation were taken. It is observed that there is significant regimentation in the treated lesion and reduction in total area of lesions.

Shashilekha Vati with *Anupana* enters to all *Sukshmastrotasas* and it acts on dash, *Dhatu* by properties of *Sukshma, Tikshna guna* and *Ushna virya*. Thus it does Diana, patina and acts as Tayca, Varna. Oil of Bakunin acts on arterioles of sub capillary plexus due to which they dilate and increase the plasma in this area. At the same time copper acts on enzyme tyrosines. Due to which melanoblasts are stimulated. They further exude and diffuse into the decolourised area and pigmentation takes place in that area. It is observed that out of 30 patients in Drug Group i.e. taking *Shashilekha Vati*, 19 patients had marked to complete (76-100%) regimentation, 7 patients had marked (51-75%) regimentation, 3 patients had moderate (26-50%) regimentation and only one patient had minimal (below 25%) regimentation. The Drug in Group A-*Shashilekha Vati* showed significant regimentation and reduction in area of lesions as compared to Group B.

KEYWORDS: *Shvitra*, *Shashilekha Vati*, Skin diseases, Vitiligo.

INTRODUCTION

Today's fastly developing world has made man to compete for a decent economical status. In order to achieve that man has to adopt constantly busy and fast life style which has its own sequels like constant physical and mental stress, tensions etc. This life style has much impact on the health of man. This busy life style is supplemented by changing food habits. Food, which plays an important role in the maintenance of health, can become poison if one does not follow healthy food habits. The major or primary reasons for skin diseases are also faulty habits.

Shvitra is one of the disease in which colour of the skin is changed to *Aruna, Tamra* or *Shveta Varna.* [1,2] The different causes have been given in the science but *Viruddha aahar* is the unique concept of Ayurveda[4], is attributed as one of the cause responsible for *Shvitra. Charaka* and *Sushruta* are of the opinion that disease of recent origin can be cured.[5]

The symptoms of *Shvitra* as described in Ayurveda can be envisaged in vitiligo, a pigmentation disorder of skin. The disease is considered as one of the social evils from times immemorial.[3] The science has proved that it is only a deformity of the skin pigment and it is not of any infective or systemic disease, but it acts as a social stigma in the society. Vitiligo is an acquired depigmenting skin condition that results from the destruction of melanocytes. It affects 3% of the Indian population. Although is only cosmetic in nature, it has a devastating effect on the psyche of the patient as it distorts the body image and causes extreme fear, anxiety and concern that is comparable to that experienced by a patient with any major illness. The disease in India has a special social significance. No single theory is above to satisfactorily explain all the various types of vitiligo leading one to believe. Vitiligo is probably multifactorial in etiology. The large majority of patients with this condition have only the cosmetic handicap, but there are others that may have

systemic association as well.[7,8] As far as the treatment remains unsatisfactory to the medical science, attempts to improve the results should be continued.

As effort is done to find out the efficacy of the drug '*Shashilekha Vati*' mentioned in *Yogaratnakar*[6]. It contains *Shuddha Parada, Shuddha Gamdhaka, Shuddha Tamra* and *Bakuchi kashaya. Parada* is *Yogavahi*. According to literary evidence, *Gamdhaka* is recommended as the most effective drug for all skin aliments. In '*Yogaratnakara'*, *Shashilekha Vati* is described in the management of *Shvitra. Shuddha Parada, Shuddha Gamdhaka, Shuddha Tamra* are taken in equal proportions. These ingredients are mixed equally and *Mardana* process done by *Bakuchi kvatha* for 24 hrs (1 Day). Then are made into tablets of 1 *Gunja* (125 mg) each. This formulation is called *Shashilekha Vati* and it is known to treat *Shvitra vyadhi*. This formulation is to be consumed with 1ml of *Bakuchi taila* and 5ml of *Madhu*.

AIMS AND OBJECTIVES

- To develop evidence based support for efficacy of textual reference of *Yogaratnakara* regarding *Shvitraghna* property of *Shashilekha Vati* with *Bakuchi* tail and *Madhu* as *Anupana*.
- To put forth the adverse reactions if any during the therapeutic trials of this drug.
- To provide effective and non-toxic drug therapy for *Shvitra*.

CLINICAL STUDY

Place of Research

The clinical study was carried out at the dept. of Kayachikitsa, Seth Tarachand Ramnath Hospital, Pune.

Study Design

- A randomized single blind controlled clinical trial was carried out in 60 patients of *Shvitra*.
- The inclusion and exclusion criteria used for the patients was as follows
- Study was carried out on patient of both groups for a period of minimum 49 days. Follow ups were kept on 7th, 14th, 21st, 28th, 35th, 42nd and 49th day.

Inclusion Criteria

1. Patients having textual signs and symptoms of *Shvitra* were selected.
2. Patients suffering from *Shvitra* were selected irrespective of age, sex, education.

Exclusion Criteria

1. Albinism
2. Generalized vitiligo
3. Cicatrix due to burns though of recent origin.
4. Skin lesions manifested by leprotic or syphilitic origin.

GROUP A GROUP B

Measures taken to minimize bias

1) Randomization procedure
2) Blinding procedure

1) Randomization Procedure

Patients were included in individual groups randomly.

Chits of group A and B were made and patients were asked to choose one unit.

2) Blinding Procedure

Patients were not aware of exact content of the drug to be administered.

Information about blinding was advised to patients during pre-trial counseling.

Dosage Regimen

Shashilekha Vati is used for drug group.

Form	**-**	*Vati*
Dose	**-**	125 mg.
Kaala	**-**	Morning, afternoon, night.
Duration	**-**	49 days.

Route of administration - Oral

The original text mentions the dose of this tablet as 1 *Nishka* = 4 *Maash* = 3.888 gms with 1 *Karsha* = 0.962 *Ratti* = 11.66 gm *Bakuchi tail* and *Madhu* as an *Anupana*.

But today, this much of the dosage seems to be larger than the needed one. Hence the dose was fixed as 500 mg *ShashilekhaVati* three times a day (1500 mg daily) with 1 ml. *Bakuchi* tail and *Madhu* as an *Anupana*.

But during our pilot study, this much of the dose also caused significant gastric irritation and itching in those subjects. Hence after discussion with the teaching faculty and senior colleagues, it was still reduced to 125 mg three times a day with 1 ml of *Bakuchi tail* and *Madhu* and the same dose was continued throughout to study.

Preparation of study Drug (*Shashilekha Vati*)

- *Shashilekha Vati* was prepared according to the method mentioned in the classical text of *Yogartnakara*.
- *Shuddha Parada* (Mercury) and *Shuddha Gandhaka* (Sulphur) in equal preparations were thoroughly mixed and made into *Kajjali*.
- *Kajjali* was mixed with *Shuddha Tamra Bhasma* taken in equal proportion.
- *Bakuchi kvatha* (*Kashaya* of *Psoralia corylifolia*) was also mixed with the above mentioned ingredients and grinding for about 24 hours.
- This mixture was then dried in a heater.

- This dried mixture was then passed through a sieve to get granules.
- These granules were then loaded in the tablet-making machine to make tables of 1 *Gunja* (125 mg) each. (Table 1)

Table 1: Ingredients of *Shashilekha Vati*

Shashilekha Vati			
Ingredients	***Shudha Parada***	***Shuddha Gandhaka***	***Tamra Bhasma***
Proportion	1 part	1 part	1 part
Mardan with *Bakuchi Kvatha*			

Note: *Kalmia manna*

1 *Karma* = 96 *Ratti* = 1 to1ã = 11.66 gm (metric)

1 *Nishka* = 4 *Mash* = 3.888 gm. (metric)

Similarly control was used of *Yastimadhu vati.* Control was also administered in the same manner.

Interim Examination

Complete history taking and physical examination was done on day 0 and on every 7th day physical examination related to *Shvitra vyadhi* was done. Final assessment was done on last day (Day 49). (Table2)

Table 2: Physical examination patient

Day Examination	0	7	14	21	28	35	42	49
Complete physical examination	✓							✓
Number of lesion	✓	✓	✓	✓	✓	✓	✓	✓
Measurement of area of lesion	✓	✓	✓	✓	✓	✓	✓	✓
Colour of lesion	✓	✓	✓	✓	✓	✓	✓	✓

Primary End Points

- Change in the colour of lesion
- Regression in *Tvak vaivarnyata* e.g. improvement in measurement of area of lesion.
- Commencement of pigmentation, which may be marginal, perifollicular, diffuse, combined in nature.

Discontinuation Criteria

- Incidence of any acute condition or life threatening disease.
- Incidence of any such disease or situation, which presents the subject from attending more than three interim examinations.

Procedure of Subject Withdrawal

- Honorary physicians in Seth Tarachand Ramnath offered subjects treatment for their condition.
- Subject were informed about their withdrawal from the trial when their condition were stable counseling was done.

Maintenance of Source Data

- Special case paper was prepared.
- Serial number and the group of the patient was reordered on the case paper.

Table 3: Treatment protocol of Patients in Group A and B

Group	**Group A**	**Group B**
Treatment given	*Shashilekha Vati*	*Yastimadhu Vati*
No. of Patients	30	30
Period	49 Days	49 Days
Route of administration	Oral	Oral
Dosage	125 mg	125 mg
Dosage scheduled	Morning, afternoon, evening	Morning, afternoon, evening

I) Medications Permitted During Trial

- Ongoing medications such as anti hypertensive, antidiabetic treatment were permitted.
- In acute condition proper treatment required for same.

Medications not permitted during trial

- Corticosteroids
- Analgesics and anti-inflammatory drugs
- Self medications
- Ayurvedic internal medication for the same disease

Assessment of Efficacy

- Efficiency parameters
- Methods and timing

Efficacy Parameters

1. Regimentation
2. Measurement of area of lesion
3. Visual Analogue Scale

The overall effect of the treatment in both the groups was assessed.

Regimentation: The nature of regimentation was classification into 4 types:

Marginal: When predominant regimentation was from the borders of patches.

Perifollicular: When predominant regimentations was follicular.

Diffuse: When there occurred generalized darkening across the patches of vitiligo.

Combined: If it did not fit into any single type or when more than one pattern contributed to the pigmentary process.

Regimentation was recorded as

Grade 0 - No change

Grade 1 - Minimal change (0 to 25%)

Grade 2 - Moderate change (26 to 50%)

Grade 3 - Marked change (51 to 75%)

Grade 4 - Complete regimentation (76 to 100%)

Measurement of Area of Lesion

Measurement of area of the lesion of the skin was done. The procedure adapted to measure area is delineated here with. The patches were traced on the trace paper with the pencil. These tracings were kept on graph paper and again these tracing of the patches were traced on the graph papers. The total squares of the graph paper covered by these tracings were counted and the total area was calculated. Those square of the graph of which covered less than half size of square of graph were not counted. However more than half size were counted for one square. Thus up to certain extent approximate size of the area was calculated.

The Photographic records of the lesions were kept.

Visual analogue scale

Visual Analogue Scale was used to assess two parameters mentioned in Ayurvedic texts namely kendo and dacha.

This is an imaginary horizontal line of 10 cm. Zero mark on left hand side and 10 on right hand side. Zero indicates absolutely no kendo or dacha and '10' indicate maximum severe kendo or dacha. Each cm indicated points from 'O' to '10'. Patients were called and asked to grade their symptom and define accordingly in number before during and after treatment.

The difference between these two points will gives rise to the effect of treatment in objective from the evaluation of the same was done at the end of the trial.

The score for Visual Analogue Scale. Score

0 – 1	0
2 – 4	1
5 – 7	2
8 – 10	3

DISCUSSION

After observing the observations and analyzing the raw data we have come to the conclusion that that drug is effective in the conducted trial. The trial was conducted on a sample size of 60 divided in two groups. In the criteria of assessment, measurement of area of lesion, nature of regimentation and degree of regimentation were taken. Visual analogue scale was used for dacha and kendo. The assessment was carried out before and after treatment to evaluate the total effect of treatment.

Discussion about general observations

1) According to sex

Female patients were more in number than male patients. It may be due to etiological factors like *Vishmashana, Viruddha Anna, Abhishandi Ahara*, *Vegavarodha* and *Divasvapa*. Hence there is vitiation of *Tridosha*, which leads to *Shvitra*.

2) According to Age

Maximum patients were belonging to *Tarunavastha* group. It may be due to disturbed food habits and increasing mental stress day by day in this age group. All have led to increase *Tridosha* giving rise to the diseased condition.

3) According to Occupation

Students and housewives had more prevalence of disease. They have tendency towards *Viruddha ahara* and *Vishamashana* which causes vitiation of *Tridosha* and cause *Shvitra*.

According to family history of *Shvitra*

Very few patients gave positive family history of *Shvitra*.

4) According to diet

Maximum patients used to take *Madhura rasatmaka* and *Snigdha gunatmaka ahara.* They also had habit of *Viruddahara*. These factors might have contributed for *Aamavridhi* and subsequent *Tridosha prakopa* giving rise to increased possibility of *Shvitra*. The incidence of vegetarian and non-vegetarian diet was similar.

5) According to *Vihara*

Majority of patients had habit of *Divaswapa* that is the important haut causing kappa and *Vata prakopa.*

7) According to *Prakriti*

Incidence of *Shvitra* was predominantly found in *Kaphapittaja prakriti.*

8) According to *Dosha dushti*

Maximum number of patients had vitiation of *Tridosha* in which predominance of kappa dash was found. It may be due to the habit of taking the diet dominant in *Madhura rasa, Snigdha guna* in maximum patients. It led to vitiation of *Kapha*.

9) According to *Dhatu* dusty

Majorities of patients had *Rasa, Rate, Mamsa* and *Meda* dusty.

10) According to dacha and *Kamdu*

Out of 60 patients, dacha and *Kamdu* were present in 5 and 12 patients respectively.

11) According to *Tvakvaivarnyata* (colour of lesion)

All the patients were showed *Tvakvaivarnyata* as *Shveta, Rakta* or *Tamra*. Out of 60 patients, 50 had *Shveta varna*, 6 had tama and only 4 patients had *Raktavarniya tvakvaivarnyata*.

CLINICAL OBSERVATION

Common etiological factors were seen as consumption of *Madhura, Snigdha Dravya, Viruddha Aahar, Divaswapa* etc.

Ayurvedic texts clearly mention the bad prognosis of chronic *Shvitra* and very good prognosis if treated in early stages, same thing is found in my research project. The patients who have consulted in early stage of the disease obtained good result comparatively to chronic patients. From this observation it can be stated that early consultation gives good result in *Shvitra vyadhi*.

It is observed that there is significant regimentation in the treated lesion and reduction in total area of lesions.

Shashilekha Vati with *Anupana* enters to all *Sukshmastrotasas* and it acts on dash, *Dhatu* by properties of *Sukshma, Tikshna guna* and *Ushna virya.* Thus it does Diana, patina and acts as *Tvacya, Varna.*

Oil of *Bakuci* acts on arterioles of sub capillary plexus due to which they dilate and increase the plasma in this area. At the same time copper acts on enzyme tyrosine's. Due to which melanoblasts are stimulated. They further exude and diffuse into the decolourised area and pigmentation takes place in that area.

In this way, *Shashilekha Vati* acts as *Tvachya*, *Varnya* and *Shvitraghna*.

Control group showed very poor result as compared to the treated group.

It is observed that out of 30 patients in Drug Group i.e. taking *Shashilekha Vati*, 19 patients had marked to complete (76-100%) regimentation, 7 patients had marked (51-75%) regimentation, 3 patients had moderate (26-50%) regimentation and only one patient had minimal (below 25%) regimentation.

In Control Group, out of 30 patients, 2 patients had moderate regimentation, 10 patients had minimal regimentation and 18 patients had no regimentation.

Out of 30 patients in Drug Group, 10 patients had perifollicular type and 3 patients had combined type of regimentation. Maximum number of patients i.e. 17 patients had diffuses type of regimentation.

Shvitra is a *Tridoshaja vyadhi* which predominantly involves *Tvakgata lasika,* rate and *Mamsa dhatu*. It also involves *Udana vayu*, *Ranjaka pita* and *Bhrajaka pita*.

All ingredients of *Shashilekha Vati* are *Kaphavatashamaka* by virtue of their *Katutikta* rasa, *Katu vipaka* and *Ushna virya*. All of these contents specifically act as *Kushtaghna* by their *Prabhava*.

Gandhaka and *Bakuchi* being *Katutikta* rasa, Kato *Vipaka* and *Ushna virya* act as *Aamapacaka* by *Agnidipana*. *Tamra* scrapes out the stuck *Aama*, in various *Strotasaas*. It also acts as *Vatashamaka* by *Madhura vipaka*. So, it helps Dana vatu to function properly. *Parada* by virtue of its Ramayana, *Yogavahi* and *Kushtaghna* property has an ability to reach all *Sukshmatisukshma strotasas* All these factors contribute for *Agnivardhana* and hence proper functioning of *Pacaka pita*. Thus good quality of *Ahararasa* is produced which intern helps further *Dhatu* to achieve the expected *Nirama avastha*. Due to which, functioning of *Raktadhatvagni* gets regulated, proper *Raktaprasadana* is done. It helps remake and *Bhrajaka pita* to function properly and giving rise to a normal colour and luster to skin respectively. As a drop of oil spreads instantaneously in water, *Anupana* helps the drug to spreads all over the body. To increase the potency of drug specific *Anupana* is advised. *Bakuci taila* is an extract of their seeds, it has a property of *Katu rasa* and *Ushna virya* and it acts as *Vyadhipratyanika Dravya* by *Prabhava*. *Madhu* is a *Yogavahi* and *Suksmastrotogami*. *Shvitra* is predominantly a disease of *Tvacha* and *Tvacha* covers all the body. *Taila* and *Madhu* helps all ingredients of *Vati* to reach all the *Strotasas* and *Dhatu*. *Taila* also acts as *Agnidipana* by *Katu rasa* and *Ushna virya.*

Shashilekha Vati enters to all minute *Strotasa* and it acts on all dash, *Dhatu* by properties of *Sukshma*, *Tikshna guna* and *Ushna virya*. Thus, it does *Dipana*, *Pachana* and acts as *Tvachya, Varnya, Shvitraghna. Shashilekha Vati* is very useful in the treatment of *Shvitra*.

RESULTS

- According to classification of degree of regimentation stated by 'American Journal of Dermatology', 't' value calculated for comparison between 'Group A' and 'Group B' is t_{cal} = 12.14, which is greater than 't' value of 't' table which is significant. Thus degree of regimentation in Group A (P=0.0027<0.05*)* is statistically significant as compared to Group B (P=0.45>0.05).
- 'P' value calculated for comparison between 'Group A' and 'Group B' for decrease in area of lesion is 0.0076<0.05, which is statistically significant. Thus, statistically it is proven that there is significant decrease in area of lesion in 'Group A' over 'Group

B'. Hence, in Group A, significant positive effects were seen such as commencement of pigmentation and decrease in area of lesion as compared to Group B.

This means, the drug used i.e. *Shashilekha Vati'* is significant as compared to '*Yashtimadhu Vati'*. Thus, efficacy of *Shashilekha Vati'* by textual method is proved.

CONCLUSION

- After analyzing all the raw data and observations, we come to conclusion that the Drug Group A- *Shashilekha vati* showed significant regimentation and reduction in area of lesions as compared to Group B. Thus it is found that Group A is highly significant against Group B.
- *Shashilekha Vati* is statistically significant in *Shvitra vyadhi.*
- *Shashilekha Vati* showed dominantly diffuse type of regimentation.
- After achieving satisfactory regimentation in *Shvitra*, it is also important to look for its stability in future. The further study regarding the ability of the drug to retain the pigment is necessary. Hence the topic is open to eminent scholars for the further study and evaluation.

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