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 Shvitra 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. Bakunin acts on arterioles of sub capillary plexus due to which they dilate and increase the plasma in this area.

Shashilekha Vati 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]

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 sequel 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 Gamdakha, Shuddha Tamra and Bakuchi kashaya. Parada is Yogavahi. According to literary evidence, Gamdakha is recommended as the most effective drug for all skin ailments. In 'Yogaratnakara', Shashilekha Vati is described in the management of Shvitra. Shuddha Parada, Shuddha Gamdakha, 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 Shvitraagha 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 7\(^{th}\), 14\(^{th}\), 21\(^{st}\), 28\(^{th}\), 35\(^{th}\), 42\(^{nd}\) and 49\(^{th}\) 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.

<table>
<thead>
<tr>
<th>Form</th>
<th>Vati</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>125 mg</td>
</tr>
<tr>
<td>Kaala</td>
<td>Morning, afternoon, night.</td>
</tr>
<tr>
<td>Duration</td>
<td>49 days.</td>
</tr>
</tbody>
</table>

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 dosage 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 (Khashya of Psorailia 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>
<thead>
<tr>
<th>Ingredients</th>
<th>Shudha Parada</th>
<th>Shuddha Gandhaka</th>
<th>Tamra Bhasma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion</td>
<td>1 part</td>
<td>1 part</td>
<td>1 part</td>
</tr>
</tbody>
</table>

*Mardan with Bakuchi Kvatha*

Note: *Kalmia manna*

1 *Karma = 96 Ratti = 1 to1â = 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 vyadi* was done. Final assessment was done on last day (Day 49). (Table 2)

<table>
<thead>
<tr>
<th>Day Examination</th>
<th>0</th>
<th>7</th>
<th>14</th>
<th>21</th>
<th>28</th>
<th>35</th>
<th>42</th>
<th>49</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete physical examination</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Number of lesion</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Measurement of area of lesion</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Colour of lesion</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Group</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment given</td>
<td><em>Shashilekha Vati</em></td>
<td><em>Yastimadhu Vati</em></td>
</tr>
<tr>
<td>No. of Patients</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Period</td>
<td>49 Days</td>
<td>49 Days</td>
</tr>
<tr>
<td>Route of administration</td>
<td>Oral</td>
<td>Oral</td>
</tr>
<tr>
<td>Dosage</td>
<td>125 mg</td>
<td>125 mg</td>
</tr>
<tr>
<td>Dosage scheduled</td>
<td>Morning, afternoon, evening</td>
<td>Morning, afternoon, evening</td>
</tr>
</tbody>
</table>

**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 pigmented process.

Regimentation was recorded as

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No change</td>
</tr>
<tr>
<td>1</td>
<td>Minimal change (0 to 25%)</td>
</tr>
<tr>
<td>2</td>
<td>Moderate change (26 to 50%)</td>
</tr>
<tr>
<td>3</td>
<td>Marked change (51 to 75%)</td>
</tr>
<tr>
<td>4</td>
<td>Complete regimentation (76 to 100%)</td>
</tr>
</tbody>
</table>

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 ‘0’ 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

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2 – 4</td>
<td>1</td>
</tr>
<tr>
<td>5 – 7</td>
<td>2</td>
</tr>
<tr>
<td>8 – 10</td>
<td>3</td>
</tr>
</tbody>
</table>

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 aghara 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 aghara. 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 Dhauty 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 Tvakvaiavarnyata (colour of lesion)

All the patients were showed Tvakvaiavarnyata as Shveta, Rakta or Tamra. Out of 60 patients, 50 had Shveta varna, 6 had tama and only 4 patients had Rakta varna tvakvaiavarnyata.

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 capillaryplexus 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 Shvitra vyadhi.

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 Tridoshasa vyadhi which predominantly involves Tvakgata lasika, rate and Mamsa dhatu. It also involves Udana vayu, Ranjaka pita and Bhraraja 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, Katu Vipaka and Ushna virya act as Aamapacaka by Agnidipana. Tamra scrapes out the stuck Aama, in various Strotasas. 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 Sukhmsatisukshma strotasas All these factors contribute for Agnivardhana and hence proper functioning of Pacaka pita. Thus good quality of Ahhararas is produced which intern helps further Dhatu to achieve the expected Nirama avastha. Due to which, functioning of Raktadhavagni gets regulated, proper Raktaprasadan is done. It helps remake and Bhraraja 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 Tvachya and Tvachya 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 Strotasas and it acts on all dash, Dhaut by properties of Sukshma, Tikshna guna and Ushna virya. Thus, it does Dipana, Pachana and acts as Tvachya, Varnya, Shvitra vyadhi. 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...
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.

**REFERENCES**


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