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EFFECT OF CERTAIN AYURVEDIC DRUGS ON VITILIGO (SWITRA) IN CHILDREN

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ABSTRACT

Since the beginning of the civilization the disease *Switra* (vitiligo) is considered to be a great social stigma and persons suffering from it could not command respectable position in society. Vitiligo affects the 1% of world population. The disease may start at any age but usually seen in childhood at 10 years of age or in second decade of life. *Switra* is considered as one of the varieties of *Kusta* in the *Ayurvedic* classics, caused due to vitiation of *Tridoshas* and *Dhatus* like *Rasa, Rakta, Mamsa* and *Meda*. Based on the sympotoms, *switra* can be correlated with vitiligo.

The present study was carried out to find the efficacy of *Chitraka* & *Sweta-Aparajita moola* with *Ewe's milk*, in bringing pigmentation in vitiligo patches. In entire study 30 patients between the age group 5-15 years attending the *Kaumarbhritya* OPD and IPD of *SDM college of Ayurveda* and hospital, Hassan with complaints of *Switra* were taken up for the study from Feb.2005 to Nov.2006. Only *Switra* subjects were selected and divided in two groups by simple randomized method & others were excluded. Treated & Placebo group were treated for two months with follow up after 1 month. Result of therapy was evaluated on the basis of improvement in signs and symptoms. For statistical analysis paired t test was applied. After treatment, there was significantly increased number of black spots in the lesion on an average by 31% and improved color of patches towards the normal on an average by 38.33% while there was 19% reduction in size of patches in treated group patient.

Keywords: *Aragvadha Phalamajja; Chitrakamool; Ewe'smilk; Khadirodak; Sweta-aparajitamoola; Switra; Vitiligo; Trikatu churn*

INTODUCTION:

The disease, *Switra* does not cause any pain, ulcer or discomfort, but it creates an inferiority complex in the person affected. Many ignorant orthodox people in India consider it as leprosy. Based on the symptoms, *Switra* can be correlated with Vitiligo. The disease may start at any age but usually seen in childhood at 10 years of age or in second decade of life. Based on some dermatological out patient records it is roughly estimated to be between 3 – 4% in India. The Vitiligo affects the estimated 1% of world population.

"Some diseases do not take life, but they just ruin it."-Stephen Rothman.

Depending upon the duration of the disease and the involvement of *Dhatus*, the disease becomes prognostically bad. While explaining *Rakta-pradoshaja-vikara*, *Switra* is also mentioned.

Vitiligo or *Switra* is characterized by milky white macules on skin. Modern medicine has developed drugs from plants mainly in Chinese medicine named *Pu-Kuc*& Egyptian fruits *Ammimajus* extract but at times may fail to bring back the pigmentation. A large group of people fail to get the achieved results and is refractory to treatment. In spite of advanced modern technology and medicine the treatment of Vitiligo is not satisfactory.

A number of *Yogas* are mentioned for the purpose of external application after *Shodhana* by many classics for *Switra*. In *Rajamartanda*, the use of *Sweta-aparajita root* is mentioned for local application. *Prof.Sastry C.H.S.* in the department of paediatrics in *S.D.M. college of Ayurveda Hassan*, suggested use of *SwetaAparajitamoola* and *Chitrakamoola* along with *Ewe's milk* locally in cases of Vitiligo and this was tried successfully in few cases earlier and hence taken for the present study. In *Caraka Samhita*, he mentioned the use of *Khadirodakapana* during *Switra* treatment. This was also included in present study.

AIM:

To find the efficacy of local application of the trial drug in bringing pigmentation in the Vitiligo patches.

OBJECTIVES:

1. To study the effect of external application of *Ayurvedic* drug compound i.e. *Sweta-aparajita mool, Chitrak mool* & *Ewe's milk* on Vitiligo patches after giving *Virechana* once. This constituted the treated group.
2. To study the effect of only *Virechana* once in *Switra* patients, followed by local placebo application. This constitutes the control group.

MATERIAL &METHODS:

Selection of drug:

Drug materials taken for the study include-

1. *Trikatu churna*
2. *Moorchita goghruta*
3. *Moorchita tilataila*
4. *Aragvadha phala majja*
5. *Sweta-aparajita root +Chitrak root+Ewe's milk*
6. *Khadirodak*

Trikatu churna: *Trikatu Churna* was taken from SDM *Ayurveda* pharmacy, Udapi, Karnataka for the study.

Moorchita goghruta

Murchita-Goghruta was taken from SDM *Ayurveda* pharmacy, Udapi, Karnataka.

Moorchita tilataila

Murchita-Tilataila was taken from SDM *Ayurveda* pharmacy, Udapi, Karnataka for the study.

Aragvadha phala majja

Aragvadha-Phalamajja was collected personally from around Hassan and was used for study.

Khadirodak

Khadir is personally brought from market and was given to patients.

Sweta-aparajita root, Chitrak root and Ewe's milk

Every time fresh roots of *Sweta-Aparajita* and *Chitraka* were personally collected from *Dravyaguna* garden of SDM college of *Ayurveda* & hospital, Hassan. Patients themselves collected *Ewe's milk.*

Aerial roots of Vata (Nyagrodha)

Aerial roots of *Vata (Nyagrodha)* were collected personally from around Hassan and used as placebo drug.

RESEARCHES DESING:

Study population:

Patients attending the OPD of SDM Hospital, Hassan with complaints of *Switra* formed the material for study.

Sampling:

Simple random sampling technique was used.

Study sample:

The patients from periphery area of Hassan, Karnataka having clinical manifestation of *Switra* (Vitiligo) were enrolled.

Sample Size:

30 patients having clinical features of Switra (Vitiligo) willingly participated in study were selected from S D M *Ayurveda* Hospital, Hassan.

Study setting:

The study was carried out at SDM *Ayurveda* Hospital, Hassan from Feb. 2005 to Nov. 2006 with due written consent of patient.

Diagnostic criteria:

Complete history and clinical examination of all patients was carried out and recorded in a specially designed proforma by the Post-Graduate Dept of *Kaumarbhritya* of SDM College of *Ayurveda* and Hospital, Hassan**.**

All these patients were screened with following routine investigations.

Blood- Hb%, CBC

Inclusion Criteria:

Patients between the age group of 5-15 years were randomly included for study. Patients diagnosed as *Switra* as per clinical features mentioned in *Ayurvedic texts* were included in the study.

Exclusion criteria:

1. White anaesthetic spots, which are characteristic of leprosy.
2. Patients below 5 years and above 15 years.
3. Old refractory cases not responding after extensive use of modern medicine.
4. Patches of one year old and patches arising on the finger tips, near nail bed and in genital area are excluded from the study.
5. Vitiligo patches complicated by eczema are also excluded from study.

Ethical consideration:

Ethical clearance was obtained from institutional ethical committee of SDM *Ayurveda* College and hospital, Hassan, Karnataka.

Time and duration of study:

The total study period was 10 months i.e. from Feb.2005 to Nov.2006.

TECHNIQUE OF DATA COLLECTION:

30 patients between the age group of 5-15 years attending the *Kaumarbhritya* OPD and IPD of SDM *Ayurveda* college and hospital, Hassan with complaints of *Switra* were taken up for study after following the criteria laid as above. Their age, sex, religion, socioeconomic status, food habits, family history, *Deha-Prakruti* etc. were noted. Where there is more than one patch of Vitiligo in any patient only one patch was selected for the study. However where improvement was found in that particular patch, patient was advised to treat other patches also with the same drug. The size of the observed patch was approximately measured in square centimeters by multiplying its breadth and length.

These 30 patients were divided randomly into two groups.

1. Group A- Placebo group- containing 15 patients.
2. Group B- Treated group- containing 15 patients.

Out of a total 30 patients taken for the study, six dropped out in middle and did not continue treatment. The left out 24 patients constituted of 11 in placebo and 13 in treated group.

TREATMENT METHODOLOGY AND SCHEDULE:

All patients of both the groups were administered the drugs as follows –

1. *Trikatu Churna* in a dose of 1gram thrice daily with *Ushnodaka* as *Anupana* was administered before food for two days prior to *Snehapana* for *Pachana* of any existing *Ama* and *Agnideepana*.
2. Starting from 30 ml per day *Moorchita Goghruta* was administered for *Snehana* by increasing it by another 30ml per day until the appearance of *Kosta Snigdha Lakshanas* as evidenced from oily and loose stools.
3. *Abhyanga* was then carried out with *Moorchita Tilataila* daily followed by *Sarvanga Swedana* (for five minutes) for three days.
4. 20 gram of *Aragvadha Phala Majja* was then administered with warm *Ksheera* on third day after *Abhyanga* and *Swedana*, in the morning in empty stomach.
5. 1 gram of *Khadirasara* was mixed with 100ml of drinking water and was advised for drinking by both groups of patients. This was advised to the patient, to be followed throughout the treatment period.

A watch was made for *Kosta Shudhi* by observing the number of stools till afternoon. After this patients of group A were advised to apply the placebo daily in the morning on the Vitiligo patches with *Ewe's milk* and were advised to expose the patches to the sunlight for 15 minutes.

Similarly patients of group B were also advised to apply the paste of the drugs daily in the morning with *Ewe's milk* and were advised to expose the patches to the sunlight for 15 minutes.

Patients of both the groups were advised to apply the paste of the placebo

and trial drugs given to them daily once for two months.

ASSESSMENT CRITERIA:

Patients of both the groups were examined initially, at the end of one month and at the end of two months for the change in the patches if any.

The criteria for assessment included,

1. Alteration in the colour of the Vitiligo patches or any black dots appearing in the white patches were recorded periodically with photography.
2. Number of dots was counted and joining of two or more dots if any was noted and recorded.
3. Change in the size of observed patch if any was also recorded.

The criteria kept for grading to observe any improvement is as following	
1. **No. of black spots in observed patch**	
a. If no black spots appear	**2**
b. If less than three spots appear	**1**
c. If three or more spots appear	**0**
2. Color changes in the observed spot	
a. No change in color	**3**
b. Dark pink	**2**
c. Appearance of blebs then changes to dark pink	**1**
d. Appearance of blebs after which black spots are seen	**0**
3. Size of the observed spot	
a. If size remains same or increases	**2**
b. 10% reduction in size	**1**
c. If more than 10% reduction	**0**

Follow up:

Follow up study, was done after complete course of treatment for a period of 2 months as and when the patients came up during which period grading and photography were carried out as main criteria.

STATISTICAL ANALYSIS:

The two months treatment statistically significantly increased the number of black spots in the lesion on an average by 31% and improved the color of the patches towards the normal on an average by 38.33% while there was 19% reduction in size of the patches.

Table No. 1. Showing overall result of all criteria at the end of 2nd month treatment

Improvement based on criteria	Group B no.of patients	%	Group A no.of Patients	%
Complete Improvement 100%	0	0%	0	0%
Marked Improvement 66-99%	0	0%	0	0%
Moderate Improvement 33-66%	6	46.16%	0	0%
Mild Improvement 0-33%	5	38.46%	0	0%
No Improvement <0%	2	15.38%	11	100%

ADVERSE EFFECT OF EVALUATION CRITERIA:

Evaluation & reporting of adverse effect was done as per guidelines of National Pharamacovigilence Program for *Ayurveda, Siddha* & *Unani* (A S U) drugs.

DATA ANALYSIS:

Statistical evaluation of data was done using mean, SD, percentage. For sta-

tistics paired t test was applied for quantitative data and for qualitative data chi-square test was applied.

OBSERVATIONS & RESULTS:

Total 30 patients were enrolled for this project. Out of a total 30 patients taken for the study, six dropped out in middle and did not continue treatment. The left out 24 patients constituted of 11 in placebo and 13 in treated group. After treatment, there was significantly increased number of black spots in the lesion on an average by 31% and improved color of patches towards the normal on an average by 38.33% while there was 19% reduction in size of patches in treated group patient. Overall the placebo had no effect on any of the criteria taken in the present study. Overall trial drug is found to be more effective in altering the color of the patch.

DISCUSSION ON EFFECT OF THERAPIES:

Effect on the number of black spots in the observed patch –

At the end of first month of treatment the effect of the trial drug compound was found to be highly significant with 7.50% improvement (p value>0.05) when compared to the effect of placebo in which the improvement was 0%.

At the end of second month after treatment the effect of the drug compound used was found to be highly significant with 31% (p value<0.001%) when compared to the effect of the placebo in which the condition get aggravated.

During 3rd month the effect of trial drug compound was found to be very highly significant with 42.50% improvement (p<0.001%) when compared to the placebo in which the improvement was 0%.

Effect on the changes in color of the observed patch –

At the end of first month of treatment the effect of the drug compound was highly significant with 18% improvement in color changes (p<0.01%) when compared to the effect of placebo, which was significant with improvement of 10.26% (p>0.05).

At the end of second and third month of treatment the effect of trial drug was highly significant with an improvement of 38.33% and 48.66% respectively (p<0.001%) when compared to the effect of placebo which continued to be significant with only 10.26% improvement.

Effect on the size of the observed patch-

Effect of trial drug proved to be significant with 4% improvement (p>0.05%) when compared to the effect of placebo, which was insignificant with 0% improvement (p<0.10%) at the end of first month.

At the end of second month the trail drug was highly significant with 19% improvement (p<0.02%) when compared to the placebo group in which improvement was 0%.

At the end of 3rd month the trail drug was highly significant with 27% improvement (p<0.05%) when compared to placebo in which improvement was 0%. Thus there is an appreciable reduction in the size of the patches in treated group.

Discussion on the effect of the trial drug on different assessment criteria's

At the end of first month of treatment improvement in the black spots was found to be 7.50% (p>0.05%) and improvement in the color was 18% (p<0.01%) but the reduction in the size (p<0.05%).

At the end of second month of treatment improvement in black spots was 31% (p<0.001%) and improvement in color was 38.33% (p<0.001%). There was 19% reduction in size (p<0.02%), which was significant.

At the end of 3rd month the improvement in number of black spots was 42.50% (p<0.001%), improvement in color was 48.66 %(p<0.001%) and reduction in size was 27 %(p<0.05%).

Overall the drug is found to be more effective in altering the color of the patch.

Discussion on effect of placebo on different assessment criteria

The effect of the placebo was insignificant with 0% improvement in black spots throughout the study.

The effect of the placebo was significant with 10.26% improvement in color alteration throughout the study.

The effect of placebo was insignificant with 0% improvement in size of the patch throughout the study.

Overall the placebo had no effect on any of the criteria taken in the present study.

PROBABLE MODE OF ACTION:

During the course of the study it has been observed that one patient of treated group developed *Visphota* and the improvement was fast in the patient.

During re-pigmentation two processes were observed, first pattern was re-pigmentation from the periphery to centre, which showed delayed reduction of size. Second pattern was where the *Mandalas* developed pigmented spots in between, later configured the normal skin color by aggregation.

The pigmentation process was quick in small *Mandalas* when compared to bigger ones. *Mandalas* having white hair (two cases) did not respond quickly to the treatment. The patches over the outer border of the palm and sole responded quickly. In the patients who followed the advised *Pathya,* of intake of sprouted green gram, relief was found earlier, even according to the recent texts tyrosine rich diet is advised.

Even after the course of the study no patient showed increase in signs and no reoccurrence was seen in treated group patients.

Interpretation:

As local application of *Chitrakamool*, increases local blood circulation. *Sweta-aparajita* may stimulate the formation of melanin and *Ewe's milk* might help for its coagulation.

CONCLUSION:

The conclusion derived from the present study is as follows

Though no *Poorvroopa, Lakshanas* are described in Ayurveda; one case of *Switra* gave pro-dermal symptoms of itching at the place where patch was developed later. This could be due to *Viruddha ahara* alone invoking auto-immunological response.The *Lakshanas* of *Doshaja Switra*, as mentioned in classics were not found in the patients taken for the study.Early improvement is seen if *Visphota* is developed on application of *lepa*.Improvement is earlier if re-pigmentation starts with pigmented spots which later configured to normal skin colour, when compared to re-pigmentation, which occurs from periphery to centre.The pigmentation process is earlier in small patches when compared to bigger one.Patches having white hairs responded late to treatment.The patches over the outer border of palm and sole respond quickly to treatment.The improvement could be earlier if tyrosine rich diet is given to the patients.Placebo group who had undergone *Shodhana* once (*Virechana*) after *Pachana, Snehana* and *Swedana* did not show any improvement; hence, *Virechana* alone may not help in treating switra. However, it needs a further study to find as to whether repeated *Shodhana* helps in *Switra* or not.Local treatment is found to be more effective after *Shodhana Chikitsa* in the present study. It is possible that local application even without *Sodhana* may help in treating the *Switra*; however, this also needs further study.The same drug compound if continued for longer time may give much better results.

Recommendations for future research:

This research work was an honest effort to verify the effect of *Chitraka* and *Sweta-aparajita* roots with *Ewe's milk* on *Switra* in children but any other view for further study is humbly recommended. Since being small sample size, this study has its own limitations so the same drug compound if continued for longer time and with adequate sample size, may give much better results.

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