ORIGINAL RESEARCH ARTICLE

EVALUATION OF THE EFFICACY OF MUKHAKANTIKAR LEPA IN HYPERMELANOSIS WITH SPECIAL REFERENCE TO VYANGA

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ABSTRACT

Background: Face is the index of mind and beautiful face attracts towards itself. In today’s modern era face value is also important for self-confidence and making once successful. Exposure to sunlight, genetic predisposition, use of cosmetics and certain drugs, hormonal imbalance are implicated in the pathogenesis of most hypermelanosis. In day to day life due to air pollution, different cosmetic using habits, stressful life, dietary changes, inclination towards junk or fast food, sleeping habits different skin problems such as hypermelanosis is seen in adolescent boys and girls. With this research interest to know the efficacy of the Mukhakantikar lepa mentioned in ayurvedic classics. Objectives: Evaluation of efficacy of Mukhakantikar lepa in hypermelanosis with special reference to vyanga.

Setting and design: Clinical trial was carried out in Seth Sakharam Nemchand Jain Rugnalaya and Aushadalaya, solapur, Maharashtra, India, from-April 2009-April 2010. Materials and methods: 60 patients either sex, between age group 18 to 25 yrs, suffering from hypermelanosis, with diffuse bronze pigmentation, mandal, Kandu and daha consciously willing to participate in the clinical trial were selected randomly and received Mukhakantikar lepa for 28 days and with follow up after every week. Clinical manifestations and results were evaluated before, during and after treatment. The Persons with state grey, scars temples and shine, patients having other major systematic and endocrinal diseases, severe cases of hypermelanosis and those were not willing to participate in the trial were excluded.

Results: On statistical analysis using t test study reveals at par efficacy of trial drug on clinical manifestations reducing \( p=0.000 \) the hypermelanosis and improving \( p=0.000 \) in skin complexion. No adverse reactions documented. Conclusion: Mukhakantikar lepa works excellently on hypermelanosis i. e. vyanga and improving skin complexion.

Key words- ayurveda, hypermelanosis, vyanga, mukhakantikar lepa

INTRODUCTION:

Ayurveda the science of life has its origin in Vedic literature, the oldest knowledge everlasting in the world. “Ayurveda” is an eternal life science and this contributes too many research works. The main aim of Ayurveda is i.e. promotion of health and eradication of the diseases.

The concept of beauty has prevailed since mankind earliest ages and but in today’s world
also beauty is one of the most valued and desirable attributes the objective nature of human beauty is timeless and ayurveda stands supreme as far as this concept is concerned.

Hypermelanosis are a group of disorders characterized by abnormally darker skin that results from increased melanin production from a normal number of melanocytes in the skin. Hypermelanosis most commonly results from exposure to sunlight. However, in day to day due to air pollution, different cosmetic using habits, stressful life, dietary changes, inclination towards junk or fast food, sleeping habits different skin problems such as “Hypermelanosis” is seen in adolescent boys and girls. In these disorders there is formation of sharply demarcated light to dark brown macules of different size and shapes affecting the sun exposed areas particularly face.

A Hypermelanosis disorder has been co-related condition in Ayurveda literature known as Vyanga1,2. According to Ayurveda ‘Vyanga’ is one of the diseases mentioned under kshudra roga and is considered as swatantra vyadhi in the Ayurvedic literature. Vyanga is a disease of skin in which there is production of painless, thin black patches on the face decreasing complexion and luster of the skin. With this research interest to know the efficacy of the Mukhakantikar lepa3 explained in our classics. Hence subject title is taken as a research work. A comprehensive study has also been made with a view of update information to understand the etiology and pathogenesis of the diseases. The formulation that is selected for the clinical trial is as follows, Mukhakantikar lepa as external application on affected area. This is a clinical study and a special clinical Proforma is prepared. A total 60 number of patients were selected for treatment available from Seth Sakharam Nemchand Jain Rugnalaya and Aushadalaya, Solapur, Maharashtra. The duration of treatment was of 28 days (4 weeks) with a follow up after every week.

MATERIALS AND METHODS
Selection of drug: Trial drug Mukhakantikar lepa is a poly herbal formulation in the form of churna extensively used to skin complexion. Seven drugs are described in Mukhakantikar lepa of Sharangdhar Samhita are combined with equal quantity and the patients were advised to apply mukhalepa defined technique of lepa application.

Procurement of the drug: Ingredients of study drug Mukhakantikar lepa namely Rakta Chandan (pterocarpus santalinus), Manjishtha (rubia cordifolia), Lodhra (symlocos racemosa), Kushtha (saussurea lappa), Priyang (callicarpa macrophylla), Vatankura (ficus bengalensis), Masoor dal (lens esculenta) were first identified and authenticated from authority at SSN Rasashala (pharmacy), solapur, maharashtra. The raw materials were collected from authorized dealers of raw drugs supplying to SSNJ Ayurveda Pharmacy.

Method of preparation of lepa: All the above mentioned drugs taken in equal quantity in the form of churana and mixed thoroughly. About 30 gms churana packed in air tight plastic bags.

Study design: A randomized, uncontrolled clinical trial study.

Study population: An accessible population of adolescence patients in SSNJRA, solapur, who were suffering from vyanga, participated in the study.

Sampling: Simple random sampling technique using lottery method. Group was done by simple random allocation.

Study sample: The patients were various area of solapur city suffering from facial hypermelanosis (vyanga).

Sample size: 60 patients having facial hypermelanosis with clinical manifestations, willingly participating in the study selected from Seth Sakharam Nemchand Jain Rugnalaya and Aushadalaya, Solapur. Determination of sample size was based on the
prevalence of vyanga patients available in SSNJRA, Solapur.

**Study setting:** The study was carried out in Seth Sakaram Nemchand Jain Rugnalaya and Aushadhalaya, Solapur, Maharashtra, India from April 2009- April 2010.

**Diagnostic criteria:** Diagnosis was done on the basis of diagnostic criteria for no. of shyamvarni mandal, size, vaivarnya, Kandu and daha present in the patients having hypermelanosis (vyanga)\(^5\). Gradation of subjective parameters were as follows (-) No any shyamvarni mandal, (+) 1 to 5 shyamvarni mandal –mild, (++5 to 10 shyamvarni mandal- moderate and (+++) 10 to 15 shyamvarni mandal as severe.

**Inclusion criteria:** The patients of either sex, having age between 18-25 yrs from SSNJRA solapur, representing with sign & symptoms of Hypermelanosis (Vyanga), Patients with diffuse bronze pigmentation and willing to participate.

**Exclusion Criteria:** The Persons with state grey, scars temples and shine, patients having other major systematic and endocrinal diseases, severe cases of hypermelanosis and those were not willing to participate.

**Ethical consideration:** Ethical clearance was obtained from the institutional ethical committee of SGRA College and hospital, solapur, Maharashtra. Approved and funded by MUHS Nasik, Maharashtra (MUHS/UDC/SS/20/2009).

**Criteria of withdrawal:** Redness of the skin, increase symptoms like Kandu, daha and not willing to continue.

**Time and duration of study:** The total study period was 1 year April 2009-April 2010. While, the duration of the clinical trial was 6 months.

**Technique of data collection:** The patients suffering from vyanga with clinical manifestations of mandal, diffused bronze pigmentation, Kandu and daha were included in the study with due consent of the patient. The patients with no any shyamvarni mandal, + shyamvarni mandal –mild, ++ 5 to 10 shyamvarni mandal- moderate and +++: 10 to 15 shyamvarni mandal –severe were only included. The sample size was decided based on the prevalence of facial hypermelanosis in solapur and willingness to participate. The patients in the SSNJRA, Solapur were thoroughly interrogated; history and facts were noted in a specialized structured clinical proforma based on Ayurvedic classical frame work incorporating physical status examination. General information about the patient and its family, chief complaints to know manifestations of disease, history of skin disease, factors relieving disease, family history, personal history to get information on diet, appetite, nidra, vyasan, allergies if any. Examination included about facial patches or macules, no. of shyamvarni madala, size, vaivarnya, Kandu, daha, systemic examination with srotas pariksha\(^4\), vishesh pariksha\(^5\) included varna, twak, sweda, Kandu, daha. Samanya pariksha examination included nadi, mal, mutra, jiva, dehoshma. Examination also included aturbala\(^6,7\) pariksha like aharshtki, satmyataha, sarata, vyayamashakti, samhanan, satwataha, pramantaha. The patients were obtained lepa to apply on affected area with milk or rose water\(^8\). The feedback obtained from the patients which included graded responses. The information of effect of trial drug obtained regularly 7 days.

**Treatment methodology and schedule:** The selected patients as per inclusion criteria were randomly selected. Methodology of the treatment for the patients as follows. All the drugs (the contents of the Mukhakantikar lepa) had taken in equal quantity in the form of churna. The patients were advised to apply mukhalepa prepared from drug with milk or rose water. The thickness of lepa should of ardhanguli pramana i.e. 0.98 cm (3/4\(^8\)of an inch). The applied mukha lepa is kept in mukha pradesha for 20 minutes after that wash
is advised with fresh water or Luke warm water. The patients also advised the technique of lepa application-Lepa application should be gently rubbed in an upward (pratiloma) or reverse direction as of the hairs over the skin to make the action of the application quick and effective. The patients were visited once in a week, assessed before, in the middle of the study. Follow up was done after 14th, 21th and 28th days.

**Assessment Criteria:** The patients were assessed before, during and after treatment on the basis of subjective and objective criteria with regards to No. of Shyamvarni mandala (black patches or macules), Size of Shyamvarni mandala (Black patches or macules), Vaivarnya, Kandu, assessed by severity of symptoms and signs presented before and after treatment. Upashaya above 75% were excellent, upashaya between 35-75% were moderate and upashaya below 35% were poor.

**Adverse effect evaluation criteria:**
Evaluation and reporting of adverse effect was done as per the guidelines of national pharmacovigilence program for Ayurveda, Siddha and Unani (ASU) drugs.

**Data analysis:** Statistical evaluation of the data obtained was done using means, standard deviation, percentage, t test for single mean using SPSS version 11.5

**Table 1:** Distribution of patients according to Sex

<table>
<thead>
<tr>
<th>Sex</th>
<th>No of Patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>19</td>
<td>32</td>
</tr>
<tr>
<td>Female</td>
<td>41</td>
<td>68</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100</td>
</tr>
</tbody>
</table>

**Table 2:** Distribution of patients according to marital status

<table>
<thead>
<tr>
<th>Marital Status</th>
<th>No. of Patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married</td>
<td>10</td>
<td>17</td>
</tr>
<tr>
<td>Unmarried</td>
<td>50</td>
<td>83</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100</td>
</tr>
</tbody>
</table>

**Table 3:** Distribution of patients according to occupation

<table>
<thead>
<tr>
<th>Occupation</th>
<th>No. of Patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Students</td>
<td>43</td>
<td>72</td>
</tr>
<tr>
<td>Housewife</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>Service</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>Business</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100</td>
</tr>
</tbody>
</table>

**Table 4:** Distribution of patients according to diet

<table>
<thead>
<tr>
<th>Diet</th>
<th>No of Patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vegetarian</td>
<td>18</td>
<td>30</td>
</tr>
<tr>
<td>Mixed</td>
<td>42</td>
<td>70</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100</td>
</tr>
</tbody>
</table>

**Figure 1:** showing patients Deha Prakruti

**Figure 2:** showing patient wise relief score in all symptoms and its percentage

Observations and results

A total 60 patients suffering from Hypermelanosis from SSNJRA, Solapur participated in the clinical trial. One patient dropped out in the course of the study. Female preponderance 68% over male 32% was seen indicating female adolescence more prone to vyanga, hypermelanosis. 17% were married, 83% unmarried, the prevalence of hypermelanosis is noticed height student concerned with physical exertion and mental exertion 72%, house wives15%, service occupation 10% and lastly business occupation 3%.

Socioeconomically 68% i.e. 41 patients were from middle class, 14% i.e. 8 patients were poor and 18% i.e. 11 patients were rich. According to the diet 70% patients were taking mixed diet and 30% were taking vegetable diet. Analysis of prakruti revealed about half of the patients were pittavata 52%, Vatapiita 22%, kaphavata 7%.

Success in the treatment was assessed by charting the reduction in the laxanas.

Table 5: Showing results of Mukhakantikar lepa in Vyanga

<table>
<thead>
<tr>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-7 days</td>
<td>First assessment showed symptomatically less significant</td>
</tr>
<tr>
<td>7-14 days</td>
<td>Second assessment showed symptoms and signs are significantly decreased</td>
</tr>
<tr>
<td>14-21 days</td>
<td>Third assessment showed symptomatically significant</td>
</tr>
<tr>
<td>21-28 days</td>
<td>Last assessment showed powerful significant</td>
</tr>
</tbody>
</table>

DISCUSSION

The study drug was selected for study according Ayurvedic classics. The lepa is very effective, easily available, very safe and easy to use and method of preparation is very simple. The unmarried females having pittavataj prakruti are more prone to hypermelanosis. The aim of the study was to assess the efficacy of Mukhakantikar lepa in adolescence having vyanga. The study drug Mukhakantikar lepa was effective in reducing the number and size of shyamvarni mandal, the laxanas like daha, Kandu in total scores and self reported manifestation of hypermelanosis. It is also increased skin complexion as known by increase mean total scores of relief in all symptoms. The results were as par with standard therapy. The study drug therapy indicating that the relief in laxanas and improving skin complexion gives better and lasting effects in the management of hypermelanosis.

Probable mode of action of study drug

The ingredients of Mukhakantikar lepa are tikta (bitter), madhura kashaya rasa, predominant sheeta veerya, katu vipaka, guru and ruksha in nature with obvious alleviating action on all doshas. Specific raktaprasadaka, twakprasadada and kushtagna plays important role in improving fair complexion and luster of the skin. The contents drug of lepa makes the skin healthy, glorious and beautiful. Vyanga is a ratak vikar in which there is viation of vata, pitta dosha and dushti of Rakta dhatu, generally Mukhakantikar lepa contents raktaprasadaka, vata, pitta shamak, kapha, Pittashamak, kushtagna, varnya drugs, acts according to their properties and action on skin, bharjak pitta & rasavaha, raktavaha srotas. Properties of drugs are opposite from samprapti ghataka so it play an important role in samprapti bhanga of vyanga. The skin colour (complexion) mainly depends on bharjak pitta and avabhasini twacha, mukhakantikar lepa bring back the balance of these factors and promote the fair complexion (varnys) of the skin. Pharmacologically drugs acts as astringent, cooling, disinfectant, blood purifying agent, antiseptic, analgesic,
aromatic useful in burning sensation in body, skin disease and blood impurities. By virtue of rasa it helps in removing agnimandya, removes kleda. These may be attributed to free radical scavenging and antioxidant activity. Kashaya nature helps to equalize the vitiated doshas, clear of unwanted metabolites (kledahara) and sandhanakara, madhura rasa influences prasadana (nourishing), improves strength and complexion. It also alleviates vitiatiated pitta and vata. By virtue of sheeta veerya alleviates daha (burning sensation). By virtue of katu vipak clear of unwanted metabolites (kledahara), meda lekhan, shodan. Thus the clinical manifestations of hypermelanosis which are mainly due to dosha vitiation will be taken care by rasa and dosha alleviating properties of mukhakantikar lepa.

CONCLUSIONS:

Hypermelanosis i.e. vyanga is more in female adolescence having pittavataj prakruti. The patients with hypermelanosis were likely to experience a substantial array of problems in social, behavioral fronts. Hypermelanosis aptly known as vyanga with predominant vata, pitta and raktadhosha vitiation. Mukhakantikar lepa is effective in management of vyanga and results at par and significantly effective on vyanga. There were no adverse reactions documented. On the whole considering the limitations of the study, present research could serve as an explorative trial on similar topics. The mukhakantikar lepa in the form of ointment or cream base can be choice of therapy in vyanga for further best results in laxanas with less duration as indicated by better scores.

LIMITATIONS

The study is limited to single geographical area. Due to shortage of time, there is only four weeks of follow up further study with longer duration for severe cases may bring out remaining positive effects of drug.

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8. Yadavaji Trikamaji editor. Commentary: Ayurveda tatvasandipika of


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