

**CLINICAL EVALUATION OF EFFICACY OF VATANKURADI LEPA IN THE
MANAGEMENT OF VYANGA W.S.R. TO MELASMA**Pratibha Mapari^{*1}, Amol Thote² and Dr. Manu R.³¹PG Scholar, Kayachikitsa Department, Parul Institute of Ayurveda, Vadodara, Gujarat.²PG Scholar, Shalyatantra, Department, Parul Institute of Ayurveda, Vadodara, Gujarat.³Associate Professor, Kayachikitsa Department, Parul Institute of Ayurveda, Vadodara, Gujarat.***Corresponding Author: Pratibha Mapari**

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ABSTRACT

The Beauty and Attraction of individual is reflected in the skins health. Skin diseases though afflicts bodily but gives lot of Psychological disturbances. Vyanga is one among Kshudra Rogas, in the disease Vyanga an important sign is the presence of Neeruja, Tanu, Shyavavarnayukta Mandala on Mukhapradesha. The disease Vyanga can be correlated with Hyper Pigmentation of skin due to over production of Melanin pigment occur in disease Melasma and the Patches of Hyper Pigmentation are seen especially on cheeks, nose, forehead and chin. **Materials and Methods:** 1.Measuring tape. 2.Graph Paper. 3.MSS[Melasma Severity Scale] 4.Modified MASI Score. **Objective:** To evaluate the efficacy of Vatankuradi Lepa in the management of Vyanga. **Study Design:** open labelled clinical study. **Study selection:** Diagnosed cases of Vyanga, were selected from Opd and Ipd of Kayachikitsa and Stree-prasuti Department of Parul Ayurved Hospital, Parul University and referred cases from other Departments. **Intervention:** Selected patients were treated with "Vatankuradi Lepa" Dose 5 gm Powdered drug +10-15 ml luke warm water or milk, for 1 month. **Main outcome measures:** Based on the assessment criteria's the parameters are graded and statistically analysed using Paired 't' test. **Results:** In this study, the subjective and objective parameter shows significant values, The objective parameter like colour & size of lesion shows significant value and there is no any change was found in case of number of lesion and no any reduction was found in number of lesions, they remain same. The Kandu and Daha was absent before and after treatment, Rookshata found before treatment was reduced after treatment Snigdghata was increases up to some extent. **Conclusion:** So the results obtained from the Statistical observation Shows that Vatankuradi Lepa has been effective in Reducing the Size and Colour of skin lesion[Vyanga]. The Number of Skin Lesions were Statistically not Significant and the effect of Medication on Modified MASI Score is Statistically Significant, thus proving its efficacy.

KEYWORDS: Vyanga, Melasma, Modified MASI Score, Vatankuradi Lepa.**INTRODUCTION**

"Ayurveda" is an eternal life science and the main aim of Ayurveda is promotion of health and eradication of the diseases.

The disease 'Vyanga' is one of the disease in "Kshudra Roga,"^[1-2] In this disease an important sign is the presence of Neeruja, Tanu, Shyavavarnayukta Mandala on Mukhapradesha. The disease Vyanga can be correlated with Hyper Pigmentation of skin due to over production of Melanin pigment occur in disease Melasma.^[4] In this, the Patches of Hyper Pigmentation are seen especially on cheeks, nose, forehead and chin. The Prevalence of melasma is varies between 1.5% and 33.3%³ depending on the population. Its Prevalence in women is around 50%-70% in Pregnancy stage and 8%-29% of women on Oral contraceptive pills. In man its 20.5-25.38% of the cases.

With this research interest to know the efficacy of the Vatankuradilepa explained in our classics. A comprehensive study has also been made with to understand the etiology and pathogenesis of the diseases. The formulation that is selected for the clinical trial is vatankuradilepa as external application on affected area. This is a clinical study and total 30 number of patients were selected for treatment available from opd and ipd of kayachikitsa and prasutidepartment, Parul institute of Ayurved, limda, vadodara, Gujrat. The duration of treatment was of 30 days with a follow up after 15 days.

MATERIALS AND METHODS**Aims and Objectives**

1. To evaluate the efficacy of VatankuradiLepa in the management of Vyanga.
2. To review the literature of Vyanga, to review the literature of Melasma on the basis of MASI.

Selection of drug: Trial drug Vatankuradilepa is a poly herbal formulation in the powder form. Seven drugs are described in Vatankuradilepa described in Sharangdhara 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 Vatankuradilepa namely Rakta Chandan (pterocarpussantalinus), Manjishtha(rubiaccordifolia), Lodhra (symplocosracemosa), Kushtha (saussurealappa), Priyangu (callicarpamacrophylla), Vatankura (ficusbengalensis), Masoor dal (lens esculenta) were first identified and authenticated from Pharmacy of Parul institute of Ayurved, Vadodara, Gujrat.

Method of preparation of lepa: All the above mentioned drugs taken in equal quantity, by making fine powdered form of churna and mixed thoroughly. About 30 gmschurna packed in air tight plastic bags.

Study design: A randomized, uncontrolled clinical trial study.

Sample size: 30 patients having sign and symptoms of vyanga that is Neruja (Painless), Tanu (Thin), Shyavarnayukta(Blackish discoloration) mandala present on mukhapradesha. with clinical manifestations, willingly participating in the study selected from Parul institute of Ayurved, vadodara, Gujrat.

Study setting: The study was carried out in Parul institute of Ayurved, Parul University, Vadodara, Gujrat. from March 2018- March 2019.

Criteria for Diagnosis

1. Acc. to modern ICD 10 L81.1 MELASMA
2. Acc. to Sushruta described in nidanasthana 13/45-46,
3. Vyanga Is diagnosed as Shyava mandala present over mukha Pradesh which are tanu and Neerujam.

Inclusion Criteria

1. Patients between the age group 30 – 60 yrs. in both gender.
2. Patients presenting with cardinal features of Vyanga like dark, irregular, well demarcated hyperpigmented macules to patches.

Exclusion Criteria

1. Patients with drug induced melasma / oral contraceptive pills.
2. Patients with endocranial metabolic disorders.
3. Pregnant and lactating women.

Ethical clearance

Ethical clearance was obtained from Institutional Ethics Committee of Parul Institute of Ayurved, Parul University, Vadodara-391760. (PIA/IECHR/2017/043) dated 17/04/2017.

Registration: This study was registered in Clinical Trial Registry of India (CTRI;www.ctri.nic.in) vide CTRI/2018/02/012221.

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 from March 2018-March 2019.

While, the duration of the clinical trial was 6 month.

Data collection: The patients suffering from vyanga with clinical manifestations of mandal, Kandu and daha were included in the study with consent of the patient. The sample size was decided based on the prevalence of melasma, history and facts were noted in clinical case proforma including 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 etc.

Examination included about facial patches or macules, no. of shyamvarnimadala, size, vaivarnya, Kandu, daha, systemic examination with srotaspariksha. The patients were obtained lepa to apply on affected area with milk or luke warm water.

Treatment methodology and schedule: The patients were randomly selected as per inclusion criteria, All the drugs of vatankuradilepa, had taken in equal quantity in the form of churna. The patients were advised to apply mukhalepa prepared from drug with milk or luke warm water. The thickness of lepa should of ardhangulipramana i.e. 0.98 cm (3/4 th of an inch). The applied mukhalepa is kept on mukhapradeshafor about 20 minutes after that wash is advised with fresh water or Luke warm water. The patients also advised the technique of lepaapplication, that it should be gently rubbed in an upward (pratiloma) or reverse direction as of the hairs over the skinto make the action of the application quick and effective. The patients were visited after 15 days.

Outcome measures/ Criteria for Assessment

A) Subjective Criteria

1. Mandalam(circumscribed hyper pigmented patches on the face)
2. Neerujam(Painless Patches)
3. Tanukam (Thin Pigmentation)
4. Shyavam(Black Pigmentation)
5. Kandu
6. Daha
7. Rookshata
8. Snigdhatta

B) Objective criteria

1. Modified MASI Score.
2. Color of Lesion.

3. Number of Lesion.
4. Size of Lesion.

OBSERVATIONS

Patients suffering from melasma from Parul institute of Ayurveda, were participated in the clinical trial, the size of sample was 30 excluding the dropouts. In this Study, there were 42 patients Screened, in that total 35 patients are taken, in which 5 patients are dropout.

40% patients do Ativyayama, 33.3% Patients do Aatapasevana, 46.7% patients had Chinta, then 33.3% patients had Krodh. (70%) Patients were in between the age group of 30 to 40 years. and Female patients were (86.7%), middle class were (50%) and 40% of the patients were in Service, Vegetarians (63.33%), The patients were taking Katu Rasa (30%) pradhana diet, (56.7%) patients were has Incidence of Post Pregnancy, Kandu & Daha were not found before & After Clinical study, Rookshata were found in 60% of total patients.

In this study, the patients had Chinta (46.7%) and Krodha (33.3%) were Aggravating Factors, and Ativyayama (40%) & Aatapasevana (33.3%) and sun exposure a major causative factor present in 33.3% patients.

In this study, size of the lesion was reduced by 0.1289% after treatment, The colour of the lesion was reduced by 26.21%. Number of lesion before treatment is remain same after treatment, Modified Masi Score of lesion was reduced by 0.3376% after treatment.

RESULT

The result of the study was that the Vatankuradilepa had highly significant effects in reducing colour & size of lesions & modified MASI score also has significant result and no any significant results were found in case of number of lesions, they remain same. The Kandu and Daha was absent before and after treatment, Rookshata found before treatment was reduced after treatment Snigdghata was increases up to some extent.

The total effect of therapy is significant statistically. The modified MASI score was reduced to 0.3376% after treatment & the colour of the lesions was reduced to 26.21% after treatment & the size of the lesion reduced to 0.1289% after treatment, total effect of therapy provided statistically highly significant.

DISCUSSION

As Vyanga is one of the kshudraroga, Hence the factors like Vataprakopaka, Pittaprakopaka and Raktadushtikara Nidana are the main causative factors for the disease Vyanga. In this study it was found that majority of patients were female, they took katu, Lavan, Amla, Rasatmak Ahara and Rookshya Ahara^[5] Bakery items, Fermented Foods, Street Foods, which are Vata, Pitta and Rakta Prakopaka Ahara.

Also 13.3% Patients follow Ratrijagarana, which is Vata Prakopaka, 40% patients do Ativyayama, which is Vata Prakopaka, 33.3% Patients do Aatapasevana which is Pitta and Rakta Dushtikara, and some of them do Divaswapna which does Tridosha Prakopa, especially Pitta Prakopa. Maximum number of Patients had the incidence of Vyanga due to Aatapasevana.

In this study, 46.7% patients had Chinta, then 33.3% patients had Krodha^[6] and remaining had Shoka and Bhaya which causes Vitiating of Vata and Pitta Doshas.

The Drug taken in the Present study is Herbal Preparation "Vatankuradi Lepa"^[7] having properties of Pittashamaka, Raktadushtihara, Twachya, Kushtaghna, Varnya etc.

(70%) Patients were in between the age group of 30 to 40 years. Because of Pitta Prodominance in this age and Female patients were (86.7%), As Incidence of Melasma is more in females than males,

The patients were belonging to middle class were (50%), Vyanga does not have any relationship with socio economic status. In the present study, 40% of the patients were in Service, 26.7% patients were labour, 20% patients were Housewife, Majority of the patients were in job, it may occur due to stress factors and then labour were in more number because of sun exposure and Atishrama also.

The patients were taking Katu Rasa (30%) pradhana diet which may causing Vata and Pittaprakopa as well as Rakta Dushti. Some of the patients were taking Lavana (26.66%) Rasa and (23.33%) patients were taking Amla Rasa pradhana diet, and majority of the patients (63.3%) were taking Ruksha Aahara which causes Vataprakopa & (33.3%) patients were taking Ushna Aahara which causes Pitta prakopa and Raktadushti and (56.7%) patients were has Incidence of Post Pregnancy, which is due to hormonal imbalance occur in pregnancy.

Kandu & Daha were not found before & After Clinical study, Rookshata were found in 60% of total patients, and snigghata were found in 40% of the total patients. As Rookshata was found more in patients, it indicates that the predominance of vatadosha in patient is more.

In this study, it was found that, Chinta (46.7%) and Krodha (33.3%) were Aggravating Factors, seen in most of the patients, and Ativyayama (40%) & Aatapasevana (33.3%) were found maximum in most of the patients, which are one of the Causative factor & Aggravating factor was found in patients. In this study 56.7% females has incidence of Melasma after Pregnancy and sun exposure a major causative factor present in 33.3% patients.

In this study, size of the lesion was reduced by 0.1289% after treatment, that is reduced slightly,

The colour of the lesion was reduced by 26.21%. The colour of lesion was not reach to normal skin colour but it was becomes lighter than before treatment. Number of lesion before treatment is remain same after treatment, showing that there is no any reduction in Number of lesions. Modified Masi Score of lesion was reduced by 0.3376% after treatment, it shows that effect of therapy was found in case of Modified Masi score, Over all effect of the therapy is that the all subjective and objective parameter shows highly significant values The objective parameter like colour & size of lesion shows significant value and there is no any change was found in case of number of lesion.

The Kandu and Daha was absent before and after treatment, Rookshata found before treatment was reduced after treatment Snigdghata was increases up to some extent.

The lepa is very effective, easily available, very safe and easy to use and method of preparation is very simple. The aim of the study was to assess the efficacy of Vatankuradilepa in Patients having vyanga. The study drug Vatankuradilepa was effective in reducing colour & size of lesions, and has significant value. The study drug therapy indicating that the relief in laxanas and improving skin complexion gives better and lasting effects in the management of Vyanga.

Probable mode of action of Drug

The ingredients of Vatankuradilepa are tikta, madhurakashaya rasa, sheetaveerya, katuvipaka also guru and ruksha in nature with alleviating Specific action on all doshas^[8-9] and Vyanga is a Raktajvikar^[12]; in which there is viation of vata, pitta dosha and dushti of Raktadhatu, generally Vatankuradilepa contents Raktaprasadaka, Vata-Pitta Shamak, Kapha-Pittashamak, Kushtagna, Varnyadrugs, has action on skin, bhrajak pitta^[13] & rasavaha, raktavahasrotas. it plays an important role in sampraptibhanga of vyanga.^[14] The skin colour (complexion) mainly depends on bhrajak pitta, Vatankuradilepa back the balance of these factors and promote the fair complexion of the skin. Pharmacologically drugs acts as astringent^[15], disinfectant^[16], blood purifying agent^[17], antiseptic^[18], analgesic, useful in skin disease and blood impurities. 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 vitiated pitta and vata.^[19] By virtue of sheetaveerya alleviates daha (burning sensation). By virtue of katuvipak clear of unwanted metabolites (kledahara), medalekhan, shodan.^[20] Thus the Vatankuradilepa helps to decrease the lakshanas of vyanga by its given specific properties.

CONCLUSION

The results obtained from the Statistical observation Shows that Vatankuradi Lepa has been effective in Reducing the Size and Colour of skin lesion[Vyanga].

1. The Number of Skin Lesions were Statistically not Significant.
2. The effect of Medication on Modified MASI Score is statistically Significant, thus proving its Efficacy.

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