EVALUATION OF EFFECT OF HERBOMINERAL CREAMS ON THE REDUCTION OF MASI SCORE OF PATIENTS OF *VYANGA*(MELASMA)

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ABSTRACT

Background: *Current practice of cosmetics is fascinated with the word "natural/organic" either for normal or diseased condition. Vyanga is one of diseases of skin that harms the cosmetic value of face at greater extent.*

Aim: *The present study is aimed at to evaluate the effect of herbomineralVarnya cream containing Manjishtha, Yashtimadhu, Laksha, RaktaChandan, Keshar and YashadBhasma in Group A while replacement of Keashar with its substitute Kusumbha in Group B with the assessment of reduction of MASI(Melasma Area and Severity Index) Score.*

Material and Method*: Total 60 patients of cardinal signs and symptoms of Vyanga were registered in the OPD of Rasa Shastra, Sir SunderlalHospital,BHU. Case performa was duly prepared and consent of each patient was taken prior to the treatment schedule. Patient were assigned to the Group A and B by the lottery method of randomization. Treatment was given for six month duration and two follow ups with the one –one month.*

Result:

The mean MASI score decreased from 14.20 to 9.15 after treatment for six months and further decrease to 8.7 and 8.3 in first and second follow up respectively with Varnya Cream A in Group A.The mean MASI score decreased from 14.01 to 10.37 after treatment for six months and further decrease to 10.13 and 9.8 in first and second follow up respectively with Varnya Cream B in Group B.

Conclusion:*No significant difference in the reduced MASI score was observed in Group A and Group B . Varnya Cream B is as good and effective as Varnya Cram A.This validated the concept of PratinidhiDravyas as laid by the ancient Acharyas and here is an cost effective option we can provide to the each and every person of the society.*

Key Words:*HerbominalCream, MASI score, Varnya Creams, Vyanga*

INTRODUCTION

"*Vyanga*" is considered as '*KshudraRoga*' in Ayurveda but it's impact on the cosmetic value of face is distracting upto greater extent. Currently available treatment is not promising to completely cure the disease. Several therapeutic modalities are being used to treat '*Vyanga*', which includes numerous topical agents, chemical peels, a variety of lasers and light-based devices. However, most treatment options have been disappointing with relatively frequent failures and relapses. [1]

The knowledge of the skin as a barrier is important from the point of view of the delivery of topical treatments for skin diseases hence we feel the need to plan a logical approach to manage the disease with more realistic way by using natural ingredients with the targeting disease specific action and depending upon the best possible base to deliver the natural ingredients to the skin in more effective manner. Amalgamation of traditional dosage forms with the modern dosage form is the need of hour. Development of natural herbomineral creams targetingthe skin lightening, cost effective, user friendly approach was thus planned and clinical study was conducted.

MATERIAL AND METHOD:

Total 60 patients of either sex belonging to 20 to 55 age group with *Vyanga* was registered in the OPD of Rasa Shastra, Sir Sunderlal hospital, Institute of Medical Sciences, Banaras Hindu University and they were invited to attend a baseline assessment during which a medical history and a physical examination was carried out. Patients were divided into two groups of 30 patients in both groups by single blinding. The study protocol reviewed and approved by Institution ethics committee with registration no. ECR/526/Inst/UP/2014 dt.31.1.2014. Informed consent obtained from each subject before enrolment. A case proforma was specially designed and duly filled with all points of history taking and physical signs.

STUDY DESIGN:

Single blind, Single centered, comparative study was undertaken. Melasma was characterized according to pattern (centrofacial, mandibular or malar) and type (epidermal, dermal or mixed) was determine using overall severity, as assessed by the Melasma Area and Severity Index (MASI).[2]

Diagnostic criteria:

Classical as well as contemporary methods was adopted for diagnosis of *Vyanga*.

Diagnosis was made on the basis of *Lakshanas* of *Vyanga*.

1. *Mukhamagatyamandalam* i.e. Circumscribed patches over face
2. *Tanukam* i.e. Unelevated pigmentation of the facial skin
3. *Shyavam* i.e. Dark brown pigmentation of the facial skin
4. *Neerujam* i.e. Painless patches

Inclusion Criteria

1. Patients suffering from classical clinical signs and symptoms of *Vyanga.*
2. Patients of either sex between 20-55 age group**.**

Exclusion criteria

1. Pregnant or breast feeding mother
2. Patients receiving hormone or corticosteroid therapy
3. Patients with history of endocrine disorders or allergies.
4. Patients taking depigmenting or whitening products (oral or topical) within the previous 6 weeks will also a ground for exclusion.

Criteria of Withdrawal

1. Redness of the skin.
2. Increase symptoms like *Kandu, Daha.*
3. Not willing to continue.

Duration of the Study

The test drug was given for six months duration to access the effect of both creams on *Vyanga* for *Varnya* effect (Skin lightening).

Dose and frequency of application of *Varnya*Cream A and *Varnya*Cream B

Sufficient quantity of the creams, depending upon the area involved was advised to apply on the face. On the basis of in vitro drug release study of *Varnya*Cream A and *Varnya*Cream B the frequency of application of creams was decided as thrice a day and accordingly advice to patients.

Parameters for Assessment of therapeutic response:

1. Relief in the subjective parameters of melasma.
2. Reduction in MASI score after the treatment.

Status of Patients

Total of 67 patients were registered for the study, out of which 7 discontinued the treatment, 60 continued the treatment and no patients developed drug reaction after application of *Vranya* Cream A and B.

OBSERVATIONS:

To explore the probable reason of this disease which could be establish as new finding or validation of previous known finding. The observations made during the study have been grouped into categories viz. demographical profile, *RogiPareeksha* and *RogaPareeksha* which are as follows:

the mean age of patients in group A was 38.13 and that of group B was 38.60. Mean weight of the patients observed was 59.85±7.69 and56.42±6.87 in Group A and Group B respectively. mean BMI of group A and group B was 22.67±2.67 and 21.72±2.57 respectively. mean height of cases in group A and group B was 162.45±5.19and 161.22±5.18 respectively.

10% of the patients were male present in Group A and 3.3% present in group B.Maximum no of patients were residing in urban areai.e. 90% in Group A and 93.3% in Group B. 46.7% of total cases complaining the family history of *Vanga*distributed as 53.3% in Group A and 40% cases belongs to Group B.80% cases of Group A and 93.3% cases of Group B were using cosmetic cream on daily basis on their faces.

Assessment of Ayurvedic parameters of patients for better understanding of *Hetusevan*, *Poorvarupa*, *Rupa* of the disease was made.

Asssement of *Prakriti* showed that maximum no of case i.e. 51.7% having *Vata- Pittaj* type of *Prakriti* 28.3% of total cases having *Pitta-Kaphaj* type of *Prakriti*rest 20%belongs to*Vata- Kaphaj*type of*Prakriti.* 50% of total cases were taking *Katu* as *Pradhan Rasa* in the form of spicy food. Total 20% cases were eating the pickles, papads ,kurkure, chips which are salty food items i.e. *LavanRasa* total 13.3% were liking the *Amla* items such as lemon, oranges etc. only 5% of total cases taking the *TiktaRasa* no cases were showing the history of *Kashaya Rasa Sevan. Vihar* such as exposure to extreme heat, sun rays, wind, travelling job etc. which are contributory to causes for *vyanga* was present in 50% and absent in 50% of total cases. 65% of total cases, were showing the history of stress, tension and worry due to one or other reason while35%) of total cases, were stress free patients due to nature, age group (students) or settled financial condition.

After completion of history of related factors responsible for the *Vyanga*, the characteristics directly related to *Vyanga* disease was analysed which are as follows

63.3% of total cases including 73.3% from Group A and 53.3% from Group B having pigmentation over epidermal layer of skin.53.3% of total registered patients have pigmentation over forehead they were distributed 70% in Group A and 36.7% in Group B. 71.7% of total registered patients who were distributed as 63.3% in Group A and 80% in Group B have pigmentation over right malar area. 66.7% of total registered patients along with 60% in Group A and 73.3% have pigmentation over left malar. 21.7% of total registered patients have pigmentation over

chin 30% of them belongs to Group A and 13.3% belongs to Group B. 23.3% of total registered patients have pigmentation over nose out of which 20% belongs to Group A and 26.7% belongs to Group B.

RESULT:

The test result of the *Varnya* Cream A and *Varnya* Cream B can be represented as

Forehead Area

Between the group comparison shows significant variation in area involvement in pigmentation of forehead before treatment, after treatment, follow up first and follow up second at p value 0.008, 0.025, 0.025 and 0.029 respectively.Within group comparison revealed that significant improvement in area involvement in pigmentation of forehead before treatment, after treatment, follow up first and follow up second at p value 0.001 and 0.020 for Group A and Group B respectively. Within group comparison for Group A revealed statistically highly significant improvement in Darkness of pigmentation of Forehead before treatment, after treatment, first follow up and second follow up at p= 0.000 .Within group comparison for Group B revealed significant improvement in Darkness of pigmentation of Forehead before treatment, after treatment, first follow up and second follow up at p= 0.02

Right Malar Area

Between group comparison showed significant difference of pigmentation over Right Malar Area before treatment and after treatment at p= 0.05 and 0.04 respectively. first follow up and second follow up showed significant differences at p=0.02.Within group comparison showed statistically highly significant improvement of pigmentation over Right Malar Area before treatment, after treatment, first follow up and second follow up at p=0.000 in both the Groups.Within the group comparison showed statistically highly significant improvement in Darkness of pigmentation of Right Malar Area from before treatment to after treatment and from before treatment to either follow ups at p=0.000 for Group A and B.

Left Malar Area

Significant improvement was observed in Area involvement in pigmentationand also the darkness of patches of Left Malar Region but comparatively more improved in Group B than Group A at p=0.000.

Chin and Nose area

Between group comparison showed no significant difference in Chin and Nose Area involvement in pigmentation before treatment, after treatment, first follow up and second follow up at p= 0.1.No complete reduction of pigmentation observed over either areas and darkness of patches in either Groups but Group A was showing significant reduction than Group B.

After the calculation of MASI score the result observed as

The mean MASI score decreased from 14.20 to 9.15 after treatment for six months and further decrease to 8.7 and 8.3 in first and second follow up respectively with *Varnya*Cream A in Group A.The mean MASI score decreased from 14.01 to 10.37 after treatment for six months and further decrease to 10.13 and 9.8 in first and second follow up respectively with *Varnya*Cream B in Group B.

Between group comparison showed no significant difference in mean MASI score before treatment at p=0.894, after treatment at p=0.286, first follow up at p=0.199 and second follow up at p= 0.169.

Within group comparison showed statistically highly significant difference in mean MASI score before treatment and after treatment i.e. 5.046 at p=0.000, before treatment and fist follow up i.e. 5.483 at p=0.000, before treatment and second follow up i.e. 5.903 at p=0.000 in Group A.

Within group comparison showed statistically highly significant difference in mean MASI score before treatment and after treatment i.e. 3.64 at p=0.000, before treatment and fist follow up i.e. 3.873 at

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p=0.000, before treatment and second follow up i.e. 4.203 at p=0.000 in Group B.

CONCLUSION:

No significant difference in the reduced MASI score was observed in Group A and Group B .*Varnya* Cream B is as good and effective as *Varnya* Cram A.This validated the concept of *PratinidhiDravyas* as laid by the ancient *Acharyas* and here is an cost effective option we can provide to the each and every person of the society who wishes to charm up their *Saundarya*(Beauty)

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Graph no 1:Reduction in the mean MASI score by *Varnya*Cream A and *Varnya* Cream B after treatment   and   two   follow   ups

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