Etiopathological Study of Vyanga With Special Reference To Melasma And Therapeutic Trial of Kinshukadi Taila And Vatapatradi Lepa.

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ABSTRACT
Background: Melasma is a photo-exposed hypermelanosis defined by dark brownish maculae with irregular shapes but clear borders on the face, forehead, and temples, and less often on the nose, eyelids, chin, and upper lips. As a result of air pollution, habits of using different cosmetics, stressed lifestyles, and nutritional changes and so on, many skin disorders, including melasma, are seen in our everyday lives.

Aims and objective: To conduct a clinical study on raktadushṭi nidana in Vyanga. To conduct upashayatmaka (clinical) trial to assess the efficacy of Kinshukadi taila and Vatapatradi lepa in the management of Vyanga.

Material and methods: Total 100 patients were registered for the study, but 92 patients had completed the trial. The duration of the therapy for each group was for 60 days. This study was conducted under the following steps- Selection of patients, General observation, Administration of drug, Follow up study, Assessment.

Result: Comparing the symptomatic improvement in both groups it was found that average percentage of relief was higher in “Group A” (21.62%) followed by Group B (15.77%). It shows that effect of therapy was more in group A in comparison to Group B. It is due to the chronic nature of disease and study duration is only two months.

Conclusion: Vatapittaja prakti, it was revealed in this study, predisposes more to Vyanga (Melasma). In a study comparing the effects of both medicines, Kinshukdi Taila and Vatapatrdi Lepa, on various signs and symptoms of Vyanga in two groups, it was discovered that “Group A” (21.62 percent) had a greater average percentage of alleviation than “Group B.” (15.77 percent).

Keywords: Melasma, Vatapittaja, Vyanga, Kinshukadi Taila, Vatapatradi Lepa.

INTRODUCTION
Ayurveda is a timeless and important science focused at alleviating human suffering. The normal and pathological states of human health are discussed in this science. Skin is the living body's beauty organ, falling under the integumentary system and serving as the body's largest external organ. The WHO has listed skin illnesses among India's most prevalent non-communicable diseases, emphasising the severity of the country's increasing skin ailments. From the prehistoric era to today's microtech era, equal attention has been paid to make it appealing. Vyanga is one of them, and it affects facial attractiveness, causing inferiority
complexes, anxiety, and isolation, among other things. Vyanga is one of the illnesses listed under Kshudraroga in Ayurveda, and it is also regarded a svatantra vyadhi. Vyanga is a skin condition that causes niruja, tanu, and syavavarayukta mandala on the mukha pradesha, reducing the complexion and shine of the skin.\(^1\) Vataja, pittaja, kaphaja, and raktaja are the four different varieties of Vyanga.\(^2\) In contemporary research, the illness has been linked to melasma. Melasma is a frequent, acquired, and symmetrical hypermelanosis marked by dark brownish maculae with irregular contours but obvious boundaries on photo-exposed regions such as the face, forehead, and temples, and less commonly on the nose, eyelids, chin, and upper lips. Different skin issues, including melasma, are observed in our daily lives as a consequence of air pollution, habits of using different cosmetics, stressed lives, and nutritional changes, such as a tendency toward junk or fast meals, bad sleeping habits, and so on. Vyanga is regarded as raktaja roga by both Maharshi Charaka and Shusruta. As a result, while Vyanga is a harmless condition for the body, it is agonising for the mind. It necessitates the use of appropriate treatment and therapy. Many treatments for Vyanga have been promoted in Ayurvedic literature, including panchakarma therapy, internal medicine, and external application.

**AIM AND OBJECTIVE**

**Aim-**

To conduct a clinical study on raktadushti nidana in Vyanga.

**Objective**

To conduct Upashayatmaka (clinical) trial to assess the efficacy of Kinshukadi taila and Vatapatrachadi lepa in the management of Vyanga.

**MATERIAL AND METHODS**

The study was conducted under a strict protocol to prevent bias to reduce the sources of error in the study. This study was conducted under the following steps- Selection of patients, General observation, Administration of drug, Follow up study, Assessment of progress. The patients for the clinical study were selected from O.P.D. and I.P.D. of NIA Hospital, Roga Nidana Evam Vikriti Vigya department. Selection was carried out on the basis of relevant history, signs, symptoms and laboratory investigations. A written information and consent form had been given to the patients. The patients were explained about the purpose, procedures and possible side-effects of the trial. Total 100 patients were registered for the study, but 92 patients had completed the trial.

**Criteria for the selection of the patient**

**Inclusion criteria;** Patients with the classical signs and symptoms of Vyanga.\(^1\) Patients of both sexes from 16 to 50 years of age.

**Exclusion criteria;** Known case of any active skin malignancy, Subjects having known chronic, contagious infectious disease, such as active tuberculosis, hepatitis B or C, HIV., Known hypersensitivity to any of the ingredients used in study drug, Cases of burns., Any skin allergy., Women those taking oral contraceptive pills therapy., Any hypo pigmentation disease., Any lesion of other skin disease.

**Withdrawal Criteria;** A patient will be considered as a drop out if he/she does not report for a follow up visit for more than 5 days after the scheduled date of visit. If the participant withdraws his/her consent for any reason. If the participant is unavailable during follow up., If the participant fails to adhere to protocol requirement. If the participant’s clinical condition worsens in spite of currently prescribed medication.
Diagnostic Criteria; The following criteria were developed to select the cases on clinical ground which is based on the signs and symptoms, described in Ayurvedika text and laboratory investigations.

All the patients were assessed on the basis of assessment criteria as follows:

Subjective and Objective Parameters: Varna (Colour), Akriti (Size), Texture of lesion (Rukshata/Snigdhata), Distribution of patches/pattern of patches,

Objective parameters: Investigations were under taken to estimate the patient’s general condition if needed: CBC

General Physical Examination; Demographic Profile; The patients registered under the trial were closely examined according to the proforma of the study. It includes name age, sex, marital status, socio-economic status, occupation, education, religion, diet & other general information about patients. After preliminary registration, patients were subjected to detailed case history and physical examination as following schedule- Chief complaints with severity and duration, History of present illness, Past history, Family history, Treatment history, Personal history, Physical examination.

Administration of Drug & Group setting; The patients were selected irrespective of their age, sex, religion, occupation etc. and simple random sampling technique was followed for grouping the patients in 2 groups.

Design: Randomized, Parallel Group clinical trial. The study had received prior approval from the Institutional ethics committee. (CTRI/2019/11/021966).

Group A: Kinshuka Taila local massage on affected part for 20 minutes once daily in night daily.

Group B: Vatapatra Lepa for local application for 30 minutes once daily in evening.

Total duration of the therapy for each group was for 60 days.

Method of application of Kinshukadi Taila:
Patients were advised to apply Kinshukadi Taila over the affected area (in proper quantity according to the size of the lesion) after thoroughly cleaning the face. Then massage it for 20 min, for the proper and deep penetration of the oil into the skin. After that it were advised to patients, washed the face with lukewarm water. This whole procedure are to be done once in a day, in the evening.

Method of application of Vatapatradi Lepa; Patients were advised to apply Vatapatradi Lepa with milk, over the affected area (in proper quantity according to the size of the lesion) after thoroughly cleaning the face. Once it starts to dry then it has to be cleaned. This was to be done once a day preferably at the day time.

Plan of clinical study:
Group A Kinshukadi tilla local application on Night duration 60 days, Group B Vatapatradi lepa local application on Evening duration 60 days.

Thickness of lepa: According to Maharshi Sharangadhara the thickness of the varnya lepa should be ardhangula.

Follow up: 4 follow ups at the interval of 15 days.

Criteria for Assessment
Drug was given to the patients for 15 days and the changes in subjective parameters were recorded after two week. The scoring pattern was adopted to assess the relief in each symptom as follows-
The scoring pattern: Colour (varna): Normal Skin colour without evidence of hyper pigmentation-0, Light Brown (Barely visible shyavata)-1, Brown (Mild shyavata)-2, Dark Brown (Moderate shyavata)-3, Black (Severe shyavata)-4.

Size (Akriti): Total absence of the manḍala-0, Less than 2 sq.cm- 1, 2 to less than 5 sq.cm- 2, 5 to 8 sq.cm -3, >8 sq.cm – 4

Texture of lesion: DRY SKIN (rukṣhata/ kharata parushata): Normal -0, Mild Dryness- Not seen but felt by touch-1, Moderate Dryness- Stretching of the skin that person feels-2, Severe Dryness- Visible dryness (Chapping of the skin) & hardness of the skin -3

OILY SKIN (snigdhata): Normal-0, Mild Oiliness- Not seen with naked eye Oiliness feel by touch No need to wash face frequently (only 1-2 times a day)-2, Moderate Oiliness- Oiliness is visible on skin Need to wash face frequently (3-4 times a day)-3

Distribution of patches; 0 to 20% - 0, 21 to 40 % - 1, 41 to 60 % - 2, 61 to 80 % - 3, 81 to 100% -4.

Total effect of therapy: Steps for calculating overall percentage of improvement of individual patient: All the BT Score of every symptom of a patient was added. All the AT Score of every symptom of that patient was added.

Overall percentage of improvement of each patient was calculated by the formula

Total BT – Total AT/Total BT X 100

RESULT AND OBSERVATION
Two trial drugs (Kinshukadi Taila and Vatapatradi Lepa) were used in this study to evaluate their effect on Vyanga with special reference to Melasma. Different statistical tests were used to analyse the effect of these drugs on Vyanga in two different groups and their comparative analysis was done.

ASSESSMENT OF THERAPY; EFFECT OF THERAPY ON SUBJECTIVE PARAMETERS; Showing the inner group comparison of effect of Kinshukadi Taila on subjective parameters in Group A. Analysis of subjective parameters of group A. Statistically considered extremely significant (p-value<0.0001) result was found in varna (14.28%) and in rukṣhata/snigdhata (59.91%). Statistically very significant (p-value <0.0001) result was found in akriti (6.04%). Statistically significant (p-value <0.0001) result was found in affected area (6.25%). [Fig. 1]

Analysis of subjective parameters of group B. statistically considered extremely significant (p-value <0.0001) result was found in akriti (10.39%) and in rukṣhata/snigdhata (42.10%). Statistically very significant result (p-value <0.0001) was found in varna (6.25%). Statistically Not significant (p-value <0.005) result was found in affected area (4.36%). [Fig. 2]

Analysis of subjective parameters of Inter Group (Group A and Group B) by Table no. 89:
In Group A and Group B on statistically comparison of effect on varna then we found that, P value was 0.0171 and U statics was 813.50 and significance level was Significant. In Group A and Group B on statistically comparison of effect akriti then we found that, P value was 0.1975 and U statics was 931.50 and significance level was Not Significant. In Group A and Group B on statistically comparison of effect on rukṣhata/snigdhata then we found that, P value was 0.1087 and U statics was 880.50 and significance level was Not Significant. In Group A and Group B on statistically comparison of effect on affected Area then we found
that, P value was 0.4905 and U statics was 1005.50 and significance level was Not Significant. [Table 1]

DISCUSSION

Every study that is not explained in terms of its nature, utility, and significance is considered incomplete. One of the six characteristics of a competent physician is the ability to communicate new information with the help of shastra references.

After completion of trial, it was observed that there was no improvement in signs and symptoms of Vyaṅga. The clinical efficacy of therapy was analysed on all signs and symptoms mentioned in the assessment criteria. The variables being non-parametric were assessed by ‘Wilcoxon matched-pairs signed-rank test’ and ‘paired t test’ respectively in intra group and in inter group were compared by “Mann-Whitney test” and ‘paired t test’ respectively. The effect of therapy on the signs and symptoms of 92 patients of Vyaṅga are as follow:

EFFECT OF THERAPY ON VARNA:-
Clinically, 14.28% relief was found in group A while 6.25% improvement was seen in group B. Statistically, extremely significant results (p<0.0001) in group A and very significant(<0.0001) in group B were obtained. In group A, the mean score before the treatment was 2.956 which improved to 2.533 after the treatment. It showed an improvement with mean difference of 0.4222± 0.4995(S.D.). In group B, the mean score before the treatment was 3.043 which improved to 2.851 after the treatment. It showed an improvement with mean difference of 0.1951± 0.3977(S.D.)

Intergroup comparison was done to assess the comparative efficacy of both groups. When group A was compared with group B on symptoms of varna, the two-tailed p value was 0.0171 that was significant. Its means there is statistical difference in the efficacy of both treatments on varna.

Clinically Kinshukadi Taila was more effective than Vatapatradi Lepa in improving the complexion of varna because Kinshukadi Taila have more drugs which have varnya property and tila taila is base of Kinshukadi Taila which have qualities like uṣṇa, tiṅkṣaṇa, vyavaya and suṣkṣma because of which it reaches up to the micro channel levels and liquefies the morbid / viscid dosha for easy elimination. It is triḍoṣaṅghna and nourishes the body. Sesame oil has a unique value because it comes under poly unsaturated fats and contains unusually large amount of linoleic acid. Linoleic acid is a powerful anti-inflammatory agent and is known to inhibit pathogenic bacteria.

EFFECT OF THERAPY ON AKRITI:-
Clinically, 6.04% relief was found in group A while 10.39% improvement was seen in group B. Statistically, very significant results (p<0.0001) in group A and extremely significant (<0.0001) in group B was obtained. In group A, the mean score before the treatment was 3.311 which improved to 3.111 after the treatment. It showed an improvement with mean difference of 0.2000± 0.4045(S.D.). In group B, the mean score before the treatment was 3.085 which improved to 2.766 after the treatment. It showed an improvement with mean difference of 0.3191± 0.4712(S.D.).

Intergroup comparison was done to assess the comparative efficacy of both groups. When group A was compared with group B on symptoms of akriti, the two-tailed p value was 0.1975 that was not significant. Its means there is no statistical difference in the efficacy of both treatments on akriti.

Clinically both drugs do not have specific effect on akriti because the size of lesion (akriti) depends on the chronicity of the disease. Vyaṅga is Kshudra Roga but it takes more time to
cure or improve. As the study duration was only for two months, so no any significant result could be found.

**EFFECT OF THERAPY ON RUKSHA/TASNIGDHATA;** Clinically, 59.91% relief was found in group A while 42.10% improvement was seen in group B. Statistically, extremely significant results (p<0.0001) were obtained in both groups. In group A, the mean score before the treatment was 1.156 which improved to 0.4667 after the treatment. It showed an improvement with mean difference of 0.6889± 0.5144(S.D.). In group B, the mean score before the treatment was 1.213 which improved to 0.7021 after the treatment. It showed an improvement with mean difference of 0.5106± 0.5053(S.D.).

Intergroup comparison was done to assess the comparative efficacy of both groups. When group A was compared with group B on symptom of ruksha/tasnigdhata, the two-tailed p value was 0.1087 that was not significant. Its means there is no statistical difference in the efficacy of both treatments on ruksha/tasnigdhata.

Clinically Kinshukadi Taila is more effective than Vatapatradi Lepa to improve ruksha/tasnigdhata because tila tailed is base of Kinshukadi Taila which have qualities like ushna, tikshna, vyavayi and sukshma because of which it reaches up to the micro channel levels and liquefies the morbid / viscid dosha for easy elimination. Tila tailed is tridoshashagna and nourishes the body. Because of snigdha property, it protects the skin from excessive dryness. It also maintains the normal moisture content of the skin. Sesame oil has a unique value because it comes under poly unsaturated fats and contains unusually large amount of linoleic acid. Linoleic acid is a powerful anti-inflammatory agent and is known to inhibit pathogenic bacteria.

**EFFECT OF THERAPY ON DISTRIBUTION OF PATCHES (AFFECTED AREA);** Clinically, 6.25% relief was found in group A while 4.36% improvement was seen in group B. Statistically significant results (p<0.0001) in group A and not significant (<0.05) was obtained in group B. In group A, the mean score before the treatment was 2.400 which improved to 2.244 after the treatment. It showed an improvement with mean difference of 0.1556± 0.3665(S.D.). In group B, the mean score before the treatment was 2.298 which improved to 2.191 after the treatment. It showed an improvement with mean difference of 0.1064± 0.3117(S.D.).

Intergroup comparison was done to assess the comparative efficacy of both groups. When group A was compared with group B on symptom of affected area, the two-tailed p value was 0.4905 that was not significant. Its means there is no statistical difference in the efficacy of both treatments on affected area.

Clinically both drugs do not have specific effect on affected area because it depends on the chronicity of the disease. Vyanga is Kshudra Roga but it takes more time to cure or improve. As the study duration was only for two months, so no any significant results was found on affected area.

Bhrajaraka pitta absorbs the dravya which is applied externally over the skin. And also illumines various shades of complexion. In human body, there are innumerable pores spread throughout the skin like a mesh. Their openings are attached to the roma kupa (hair follicles) which carries the sveda and rasa dhatu inside and outside to nourish them. Through them, the active principle of medications to the skin in the form of abhyanga, parismeeka, avagaha, lepa etc. Are absorbed after undergoing paka by bhrajaraka pitta situated in the skin^4.

Most of the drugs of formulation of group A i.e. Kinshukadi Taila are madhur, kashaya, tikta rasatmaka, shita virya, katu vipaka and kapha-pitta shamaka. Also, the content of formulation possess the affinity towards rakta dhatu. Hence, it can be said that the drugs are predominantly acting on Pitta dosha, rasa and rakta dhatu and subsequently on vata and kapha.
Vatapatradi Lepa drugs have property like shitaviryata of lodhra and raktachandana which subside the aggravation of raka and pitta. Kushtha and daruharidra are having usha virya property to counteract the aggravation of vata and kapha. Kushtha has tikta and madhura rasa because of that it acts vataghna and due to snigdha and ushna guna it acts as vataghana. Moreover, lodhra have kapha-pittahara, shothahara, kushtthagha, rakta stambhaka, and vrana ropana properties. Thus, all this combined action of the drugs ceases the production of Vyanga and subsides the production of further Vyanga at the site.

CONCLUSION
This research uncovers a wealth of information on Vyanga. According to the Nidantmaka research, the majority of the individuals (40%) were between the ages of 16 and 25. Females are the most common victims of Vyanga, accounting for 54 percent of all cases. The illness affects married people, those who live in jangala desha, and people who are under a lot of psychological stress at work. Similarly, upper-middle socioeconomic groups, graduates, and those who are accustomed to sleeping during the day are the most often impacted. It was discovered in this study, vatapittaja praki predisposes more to Vyanga (Melasma). The effect of both the drugs i.e. Kinshukadi Taila and Vatapatradi Lepa in various sign and symptoms of Vyanga in two groups was found that average percentage of relief was higher in “Group A” (21.62%) followed by Group B (15.77%).

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