



SUBHADRA

INTERNATIONAL JOURNAL OF AYURVEDA

"A PEER REVIEWED SCIENTIFIC RESEARCH JOURNAL OF AYURVEDA"

(AN OFFICIALLY PUBLISHED BY HON.SHRI.ANNSAHEB DANGE AYURVED
MEDICAL COLLEGE, POST GRADUATE & RESEARCH CENTER, ASHTA)

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A RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF PUGAPHALA TWAK GHRITA IN VYANGA

- 1) Dr. Renju S., Associate Professor, Dept. of Rasa Sastra and Bhaishajya Kalpana, SCPM Ayurveda Medical College and Hospital, Haripur, Gonda, Uttar Pradesh.
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ABSTRACT :

There is a great demand for Ayurveda in the field of cosmetology due to its unique concept about Beauty; and effective with cheaper and long lasting beauty therapy with minimal side effects. So first part of the thesis “Cosmetic approach in Ayurveda” has been selected to study the whole aspect of Ayurvedic cosmetology in detail. As the field of cosmetology is so vast, to aid focus on one subject, the disease Vyanga has been selected for the present study. Among the Personality damaging disorder or disbeautifying conditions, Vyanga is such a condition which affects the Beauty as well as Personality of a person, and therefore it makes a great cosmetic importance. Nowadays Vyanga becomes one of the major issue among individuals. Vyanga is described as one of a kshudraroga in our samhithas 2,3,4 is characterized by painless, macular, blackish/brownish discolouration of the skin. 5 The clinical presentation of vyanga closely comparable to the presentation of dermis chloasma or melasma in modern parlance.

Acharya Charaka gives Bahiparimarjana chikitsa for twakgata roga . Classical texts have told different herbs and formulations to manage vyanga. According to Acharya Vagbhata, the best medicines for people living in a locality is that one grows in that particular location. Traditional folklore medicines is recognized as the way to learn about the potential of future medicine. Puga (Areca catechu Linn.) is one such potential drug with unexplored medicinal values. Modern texts indicate the use of fruit of Areca catechu Linn. externally for skin disorders. Folklore practices and books indicate the use of ripened fruit pericarp juice of puga processed with ghrita in vyanga. A cream prepared from E wax, PEG 150 stearate, EDTA, Teel oil, Glycerine and preservative was used as a Control drug. Both the drugs were analysed and standardized.

The patients were told to apply this cream twice in a day. Total 200 patients of known Vyanga were divided into 2 groups and a randomized controlled double blind clinical trial was conducted. The final results were statistically analyzed and evaluated. Though the results were encouraging in both the groups the trial group showed better results than the Control group.

Introduction :

Good skin makes you feel beautiful. Good skin helps you become more confident. Good skin is a key component of overall beauty and good health, and it can also affect your emotional and mental well-being. From acne as a teenager to fine lines in middle age, skin problems can affect your confidence and self-esteem. When you have healthy skin, you are able to face daily activities and life's challenges with more confidence. Good skin is part of a healthy lifestyle too. Unhealthy habits take a toll on us both physically and emotionally. A poor skin care regimen, frequent breakouts, age spots, fine lines and other skin issues can be symptoms of an unhealthy overall lifestyle.

The "Skin Ego"¹ is part of our specific identity, it expresses the mutual relationship between our psyche, thoughts and emotions and the skin and it is part of the most 2 modern trends in cosmetic care. Our perception of our body influences whether and how we accept our identity. This positive relationship with the body, which is a true driving force of life, in fact shapes our relationship with others.

Vyanga has been described under Kshudra Roga as Aruja (painless), Tanu (thin layered), Shyava (Dark coloured/Brown) or Shyamal (Dark coloured/black), Mandal (circular patches) that appear on the face.² It is caused due to anger, physical exertion which vitiates Vaat and Pitta dosha and which in turn reflects on the face in the form of Vyanga. Kshudra roga are generally non significant, small diseases and yet we see that these diseases are difficult to get rid off.

Melasma which is similar to Vyanga is nothing but hypermelanosis of the skin caused due to human melanogenesis.³ It reflects on the skin in the form of light to dark brownish patches on the cheeks, nose, forehead, chin and even upper lip. This melanogenesis is caused due to number of reasons such as exposure to sun, hormones, genetic, etc.

Statistics show that in Northern India 6.9% , Western India 10.8% adults have pigmentary disorders whereas in Southern India 3.28% suffer from hypopigmentary disorders and 1.54% have hyper pigmentary disorders.^{4,5}

Multiple therapies are available in both Ayurveda and Modern medicine for treating Vyanga (Melasma). I wanted to prepare a formulation which would be economical, feasible, easy and ready to use and also easy to carry around. So, after giving a deep thought to all the pros and cons of the drug formulation that could be useful as well as acceptable to the current population of Vyanga I decided to prepare an Ayurvedic cream which is pugaphalatwak ghrita.

To find a relation between Prakruti and Vyanga, “Prakriti examination” was conducted and keeping in mind the psychological effects of skin disease on people the “Quality of life Questionnaire” was also taken into consideration.

This study attempts to find a true remedy for Vyanga, to evaluate the various causes that could have triggered them, to see the role of diet in curbing them and to observe the after effects too when the treatment is stopped.

AIM :

To study the efficacy of Pugaphala twak ghrita on vyanga.

OBJECTIVES

- To correlate Vyanga with Melasma
- To prepare pugaphala twak ghrta
- To standardize the Pugaphalatwak ghrita
- To evaluate the efficacy on signs and symptoms of Vyanga (Melasma)
- To see the effects of the drug on the Quality of Life of the patient.

HYPOTHESIS :

Pugaphala twak ghrita is more efficacious than the Control Group in treating Vyanga.

NULL HYPOTHESIS

There is no difference between the efficacy of Pugaphala twak grita and the Control Group.

MATERIALS AND METHODS :

1. Raw material collection
2. Raw material Authentication
3. Raw material Analysis
4. Drug pharmaceutical preparation
5. Drug Analysis
6. Clinical Trial

1. Raw material collection :

Puga phala will be collecting from nearby areas during the season.

2. Raw material Authentication :

All the raw materials will send to a Botanist for Authentication.

3. Raw material Analysis :

All the raw materials may subject to the following tests :

1. Organoleptic characterization
2. Moisture Content⁶
3. Ash value⁷
4. Water soluble extractive value⁸
5. pH⁹
6. Phytochemical analysis
7. Total viable Aerobic count
8. Pesticide Residue
9. Heavy metal testing
10. HPTLC

Pharmaceutical preparation of drug:

Name of preparation	Pugaphala twak ghrita
Purpose	For Clinical study
Reference	Yogamrutham
Date of Starting	

Date of completion	
Equipments	Pounding machine , Gas stove, Containers, Tray, Clean fine cloth, Spatula
Ingredients	Pugaphala twak swarasa- 6L Ghrita-1.5L

Method of preparation :

Ripened Puga phala collect from nearby areas will wash and clean properly. The outer pericarp of Pugaphala(3Kg) should scraped out by using knife and it was pounded well and macerated with a little amount of water to obtain swarasa (6 L). A wide mouthed vessel was placed over mild fire and Goghrita added. When fumes start appearing in sneha, the Pugaphalatwak swarasa was added carefully to it. Boiling was continued with frequent stirring until sneha siddhi lakshana appeared in it. Later it is filtered through a clean cloth and preserved in a glass container.

Observation :

- 1) Colour
- 2) Characteristic smell.
- 3) Volume of the Pugaphala Ghrita

Precautions :

1. Heating with low flame.
2. Regular stirring should be done to avoid carbonization of the material used in the practical.

II. PREPARATION OF CONTROL DRUG : Batch I**Equipments :**

2 Steel vessels, Gas stove, Spoon, Digital weighing machine, Glass measuring beakers, Knife, Spatula, Dropper, Blender.

Ingredients :

1. Water - 750gms
2. Teel oil - 250gms
3. Glycerine - 62.5gms
4. E wax - 60gms
5. PEG 150 stearate - 60gms
6. EDTA - 7.5gms
7. Sodium benzoate as required
8. Lavender oil - few drops
9. Colour - Brown

Procedure:

- 1) Boil water in a steel vessel
- 2) Then finely cut E wax and PEG 150 stearate were added to the water.
- 3) This mixture was stirred continuously till they dissolved completely.
- 4) When the mixture becomes smooth, heat was stopped.
- 5) Then Teel oil and Glycerine were added and mixed well.
- 6) When mixture cooled down EDTA, sodium benzoate and lavender oil was added.
- 7) Finally brown colour was added drop by drop.
- 8) The mixture was then blended with a blender till fluffy cream was obtained.

Observation :

Colour

Touch

Smell

Stability studies

The creams before preparation , a small quantity of cream may prepare to check for its shelf life at room temperature. Approximately 30 grams of cream of control group will keep in 2 sterile air tight containers in a cupboard. Every 15 days it may open and observe for any changes like the oil from the cream is separating after a period of time or not.

ANALYSIS OF THE PREPARED DRUGS :

The pugaphalawak ghrita and Control cream will be prepared in different batches as required from time to time. All these batches will be analyzed with respect to following tests:

1. Organoleptic characters (Colour, Odour, Touch)
2. pH
3. Acid value
4. Peroxide value
5. Moisture content
6. Total viable aerobic content
7. Test for Aflatoxins
8. HPTLC

Clinical Study:

- **Study Design** : Randomized Controlled Parallel Double Blind Experimental Study.
- **Total Sample size** : 200 patients divided in two groups. Groups : 2
 1. Drug group ie. Pugaphalatwak ghrita : n=100 patients
 2. Control group ie. Control cream : n= 100 patients

Randomisation¹⁰ is the process of assigning clinical trial participants to treatment groups such that each participation has a known (usually equal) chance of being assigned to any of the groups.

In this case there are two study groups, one drug group and the other control group. After the drug preparation a third party had numbered the medicines both study and control (say 1 to 10) and the list of the same was kept in an envelope and sealed. Also since 5 bottles were needed for each patient to complete the trial, (as the patient would be given medicine for each visit), one number was assigned to 5 bottles of the same group at a time. This was to ensure that a person once assigned to a particular group would receive the medicine of that group itself. These numbers that were assigned to the medicines were then written on chit blocks, folded and kept in a bottle. When a patient was recruited for this trial after passing the inclusion and exclusion criteria he/she was told to pick any chit from the bottle in order to assign him/her to one of the study groups. The number he/she picked would assign him/her to

that particular group and the patients would then be given medicines of that number until the trial ends. This is a simple randomization technique.

Blinding : Double Blind Method ¹¹

A double-blind study is one in which neither the participants nor the experimenters know who is receiving a particular treatment. This procedure is utilized to prevent bias in research results. Double-blind studies are particularly useful for preventing bias due to demand characteristics or the placebo effect. The drugs after manufactured were given to a third person/party to number. They numbered the drugs, both control and study after making a list of random numbers, assigning them to each group. For eg. If 50 bottles each, of drug as well as control group were prepared. And each patient needs 5 bottles then 100 bottles can cater to 20 patients and so 20 numbers will be assigned to these bottles. (1 to 20). Now the third party will randomly group these numbers. Say, 1,4,2,6,8,10,14,15,17,20 for drug group and the rest 3,5,7,9,11,12,13,16,18 and 19 to control group. This grouping of numbers is sealed in an envelope by the third party and handed over to me. Now, when a patient picks up a chit from the bottle to select a group for himself/herself, they automatically are assigned to a particular group which is both unknown to the researcher as well as to the participant/patient. And this is known as double blinding method. This blinding is broken only at the end of the trial or if any patient gets a severe adverse reaction. Blinding helps in unbiased assessment of study. This holds true especially in case of subjective assessment parameters.

Mode of administration of drug :

Topical application on the affected part of face. Before the application, the face should be washed and wiped well.

Frequency of application : Twice daily. Morning and night or afternoon and night

VISITS & DURATION OF STUDY

Visits :

Day 0 - 1 st Visit, Day of Enrollment

Day 21- 2 nd Visit/ 1st Follow up

Day 42 – 3 rd Visit/ 2nd follow up

Day 63 – 4 th Visit / 3rd follow up

Day 84 – 5 th Visit / 4th follow up

Day 105 – 6 th visit /5th follow up/ Completion of treatment

Day 135 - 7 th Visit /6th follow up/ Follow up post treatment completion

Total number of visits : 7

Total no. of follow up : 6

Total Duration of study : 135 days

ETHICS COMMITTEE APPROVAL :

The clinical trial was initiated only after taking the Institutional Ethics Committee approval.

PATIENT SELECTION CRITERIA

Inclusion Criteria

1. Age: 20 to 50 yrs Belonging to either of the sex
2. Patients having classical symptoms of Vyanga (melasma).
3. Patients not using any topical treatment for melasma for 2 weeks prior to enrollment in the study.
4. Must provide written informed consent and comply to the protocol

Exclusion Criteria

1. Pregnant women, nursing mothers.
2. On treatment of any topical depigmenting agent within 2 weeks prior to enrollment.
3. Patients who have taken topical or systemic steroids within 1 month prior to enrollment.
4. Patients who have taken topical tretinoin within 3 months or topical hydroquinone within 6 months prior to enrollment.
5. Under treatment for another dermatological condition.

Diagnostic Criteria

1. Having classical symptoms of Vyanga
2. Shyaav-Brown patches
3. Painless
4. Thin-non elevated
5. Involving only face

Assessment Criteria

1. Melasma Area and Severity Index Score (MASI Score)
2. Physicians Global assessment Scale (PGA) 0-6
3. Patients Assessment Scale 1-3
4. Melasma Severity Scale 0-3
5. Fairness meter test 1-7
6. Clinical response to treatment scale -2 to 2
7. Photographs
8. Quality of life will be assessed using a Quality of Life questionnaire All the scales above ie. No. 1-5 are used as per the ideal guidelines for melasma.

Withdrawal Criteria

1. Request of the patient
2. Repeated protocol criteria violation and non compliance.
3. Lost to follow up
4. Also if the subject does not apply the medication for a week at a stretch he will be withdrawn from the trial.
5. If any serious adverse effects arise during the study, the medication will be stopped and the patient will be withdrawn from the study.

Screening Procedure/Visit 1:

- Patients coming in the Out patient Department will be considered for trial.
- During the first visit they were screened to see if they could be enrolled in the trial on the basis of the inclusion and exclusion criteria.
- If they fitted into all the criteria then they were recruited in the trial. If they did not fit the trial then they were excluded from the trial.
- Once recruited, the patient was explained the trial in the language best understood by him or her. Patient Information sheet about the trial was handed over to him/her. This information sheet contained my contact number so that patient could contact me for any query. If the patient wanted to discuss it with his/her family, time was given accordingly. If the patient understood then itself then an Informed Consent Document

was handed over to him or her to be signed that he understood whatever has been explained to him or her about the trial by the doctor and that he consented to participate in the trial. Also that he had the right to leave the trial whenever he wished.

- On signing the Informed Consent Document(ICD) the patient got included in the trial.
- Then the case record form was filled with the patient's case history details. Detailed history regarding the patient's diet, habits was noted down. Any related causes was enquired about. All the scales were assessed. Quality of life score form will be filled.
- Melasma Severity Scale, MASI Score and Fairness meter scale is measured and the score given.
- Lastly the photos of the patient's picture of face was clicked.
- The bottle containing the numbered chits of the medicine was then given to the patient and he was told to pick one chit. The number in the chit was the pugaphalatwak ghrita to be given to the patient. Immediately patient was assigned to a particular group unknowing to the patient or the doctor due to the double blind procedure.
- The drug was then given to the patient and explained how to apply the ghrita. The patient was also explained to inform and be alert about any reaction or untoward action that might occur after application of the cream and if so happens to inform the doctor and stop the medicine immediately.
- The date of the next visit is intimated to the patient.

Follow up Visits of Patients.

- Patient had follow up after every 21 days. Total 6 follow ups. The last follow up is after 30 days. It was to see if the patient had relapse of symptoms after stopping the medication at Visit 6.
- At each follow up visit, from Visit 2 to Visit 6, the patient is first asked about any reactions or discomfort that they might have experienced. If there were then these were noted in the Case Record Form.

Adverse Events

- Any reaction that the patient experienced were noted in the Case Record Form and after assessing whether they were serious or not, the patients were either continued or discontinued from the trial.

Missed Doses

- Patients will get explained the need to apply the cream regularly without missing.

Scales assessed at each Visit

At each follow up visit Patient's Assessment scale, Physician's Assessment Scale, Clinical Response to Treatment Scale, MASI Score, Melasma Severity Scale and Fairness Meter Scale reading will be taken.

Fairness Meter Scale:

This scale is used to measure the darkness or fairness of the skin. According to Ayurveda to measure the Shyavta of Vyanga(Melasma), to see the improvement or worsening of this condition during each visit. This scale ranges from 1 to 7, where 1 is lightest and 7 is darkest. For this Fairness Meter of Fair and Lovely fairness Cream Packet was used.

Melasma Severity Scale

This scale measures the darkness or shyavta of Vyanga (Melasma) lesions. It ranges from 0-3 where,

- 0 = melasma lesions almost equivalent to surrounding normal skin or with minimal residual pigmentation;
- 1 = mild, slightly darker than surrounding normal skin;
- 2 = moderate, moderately darker than surrounding normal skin;
- 3 = severe, markedly darker than surrounding normal skin.

MASI SCORE

It is the Melasma Area and Severity Index Score (MASI). It is developed by Kimbrough-Green et al for the assessment of Melasma. The severity of the Melasma in each of the four regions (Forehead 30%, Right malar region 30%, Left malar region 30% and Chin10%) is assessed based on three variables:

1. percentage of the total area involved (A),
2. darkness (D), and
3. homogeneity(H).

A numerical value assigned for the corresponding percentage area (A) involved is as follows:

- 0 = No involvement;

1 = 10% involvement;

2 = 10-29% involvement;

3 = 30-49% involvement

4 = 50-69% involvement;

5 = 70-89% involvement;

6 = 90-100% involvement;

The **darkness of the melasma** (D) is compared to the normal skin and graded on a scale of 0 to 4 as follows:

0 = Normal skin color without evidence of hyperpigmentation;

1 = Barely visible hyperpigmentation;

2 = Mild hyperpigmentation;

3 = Moderate hyperpigmentation;

4 = Severe hyperpigmentation.

Homogeneity of the hyperpigmentation (H) is also graded on a scale of 0 to 4 as follows:

0 = Normal skin color without evidence of hyperpigmentation;

1 = Specks of involvement;

2 = Small patchy areas of involvement 2 cm diameter;

3 = Patches of involvement >2cm diameter

4 = uniform skin involvement without any clear areas

To calculate the MASI score, the sum of the severity grade for darkness (D) and homogeneity (H) is multiplied by the numerical value of the areas (A) involved and by the percentages of the four facial areas (10-30%).

Total MASI score = Forehead 30% (D+H)A + Right malar 30% (D+H)A + Left malar 30% (D+H)A + Chin 10%(D+H)A .

So MASI Score gives us the score given to the combined effects of Melasma, area involved (vyapti), darkness (shyavata) and the type of distribution.

Physicians Global Assessment Scale (PGA)

This Scale applies to the changes observed by the Physician in the Patient's condition. The Scale ranges from 0 to 6, where 0 is clearance of any symptoms and 6 is the worse condition. The description of the scale is as follows:

0 = Clear, except for possible residual discoloration.

1 = Almost clear, very significant clearance (90%); only minor evidence of hyperpigmentation remains.

2 = Marked improvement, significant improvement (75%); some disease evidence of hyperpigmentation remains.

3 = Moderate improvement, intermediate between slight and marked improvement; (50%) improvement in appearance of hyperpigmentation

4 = Slight improvement, some improvement (25%); significant evidence of hyperpigmentation remains.

5 = No improvement; hyperpigmented condition unchanged.

6 = Worse; condition worse than at baseline.

Patient's Assessment Scale (PA)

This Scale gives a glimpse of a Patient's perspective about the relief they have witnessed about their condition. This scale ranges from 1 to 4, where 1 is very good improvement and 4 is no change. The description of this scale is as follows:

1 = Marked/Very good improvement(> 75%)

2 = Moderate/Good improvement (>50-75%)

3 = Mild/Less improvement(>25 - 50%)

4 = No improvement (0-25%)

Clinical Response to Treatment Scale (CRT)

This Scale attempts to study the effect of the Treatment given. It ranges from 12 to 2, where below 0 ie. the negative number implies the worsening of condition and above 0 ie. 1 and 2 imply the improvement of condition. The description of the scale is as follows:

-2 = Much worse

-1 = Worse

0 = No change

1 = Improved (Upto 50%)

2 = Much improved (> 50%)

At every follow up visit fresh bottle of medicine was given to the patient. Medication was stopped at Visit 6 and patient called after a month on Visit 7.

Visit 7

On the last visit ie.Visit 7, Patient's Assessment scale, Physician's Assessment Scale, Clinical Response to Treatment Scale, MASI Score, and Fairness Meter Scale reading 94 were taken. This was compared with the results of Visit 6 to see if there is any relapse or not. Some patients did not come for the last visit, then for such patient's follow up will be taken on the phone to see whether any relapse was observed and the same was noted in their Case Record Form.

Quality of Life Score

This Form will be filled first on Visit 1 and then on Visit 6. The Scores of these 2 visits were finally calculated. This form comprised of a questionnaire which was filled by the patient itself. The score was then calculated by the physician. The Scores were assessed as following:

0 to 1 = No effect on Patient's life

2 to 5 =Little/Minimal effect

6 to 10 = Moderate effect

11 to 20 = Very large effect

21 to 30 = Extremely large effect

STATISTICAL ANALYSIS OF THE STUDY :

The clinical trial was assessed on the basis of following 6 scales

1. Fairness meter. Scale 1 to 7

2. Melasma Severity Scale 0 to 3

3. MASI Score: As per the calculation

4. Patient's Assessment Scale 1 to 4

5. Physician's Assessment Scale 0 to 6

6. Clinical Response to Treatment Scale⁻ 2 to ⁺2

7. Quality of Life Score. The data that was collected according to the given scales was Non Parametric data and so for Intra Group ie. Assessment within a group during various visits was done by using Friedman test and Inter group assessment between both Trial and Control Group was done using Mann Whitney's Test. Fairness Meter Scale: Friedman Test applied for Intra group assessment of Trial Group: Fairness Meter Scale.

Friedman Test applied for Intra group assessment of Control Group: Fairness Meter Scale.

Mann Whitney Test applied for Inter group assessment between Trial and Control Group: Fairness Meter Scale.

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